IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARD LIFESCIENCES, LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE, LLC, Defendants.	)	C.A. No. 08-091-GMS REDACTED: PUBLIC VERSION

HIGHLY CONFIDENTIAL DECLARATION OF RHONDA ROBB

OF COUNSEL:
Robert A. Van Nest
Brian L. Ferrall
Dan Jackson
Simona A. Agnolucci
KEKER & VAN NEST LLP
633 Battery Street
San Francisco, CA 94111
(415) 391-5400

Dated: December 13, 2013

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
David M. Fry (No. 5486)
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
dfry@shawkeller.com
Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT

IN THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES, LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE, LLC, Defendants. AND RELATED COUNTERCLAIMS.	Case No. C.A. No. 08-091 (GMS)

HIGHLY CONFIDENTIAL DECLARATION OF RHONDA ROBB

I, RHONDA ROBB, declare under penalty of perjury that:

1. I currently hold the title of Vice President and General Manager, Catheter-Based Therapies at Medtronic, Inc. Among my responsibilities is the development of Medtronic's global business for the Medtronic CoreValve transcatheter aortic valve replacement (TAVR) product. I have held this position since 2009. In this role, I regularly visit and speak with physicians around the world who are using the CoreValve® device, as well as many physicians who use or are familiar with both Edwards' Sapien 9000TFX and the Sapien XT device. The Sapient XT device recently was introduced commercially in Europe but is still in a clinical study in the U.S. and is not approved by the Federal Drug Administration ("FDA") for commercial sale in the US.

2. This declaration supplements the declaration I previously submitted to the Court in this matter on June 24, 2013. Except where indicated, I have personal knowledge of, and could testify under oath to the matters set forth below if called upon to do so.

3. The Center for Medicare & Medicaid Services ("CMS") has established a set of extensive requirements and criteria with which hospitals must comply in order to be covered (reimbursed) for TAVR procedures. Such procedures can use any company's TAVR products that have an FDA approved indication for commercial sale or products under investigation that meet the criteria as set forth by the CMS National Coverage Determination.[1] Among other things, TAVR-qualified hospitals must have heart teams consisting of both a cardiovascular surgeon and an interventional cardiologist with certain relevant surgical and procedural experience. In order to remain TAVR-qualified, hospitals must have performed at least 20 TAVR procedures in the prior year or 40 TAVR procedures in the two prior years, using any combination of available TAVR products, including TAVR products commercially available and those TAVR products still in clinical studies and not yet approved by the FDA. Accordingly, hospitals must invest significant time and effort in securing the required infrastructure (on site

[1] http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&ver=1.

surgery, procedural/imaging equipment and space, and post procedural facilities) to meet CMS requirements. Only a finite number of hospitals in the United States have met CMS's criteria.

4. Based on prior review of research reports and data, Medtronic has estimated that only approximately 350-400 hospitals in the United States meet these CMS criteria and are qualified to perform TAVR procedures.

5. Training physicians in a TAVR procedure using the CoreValve THV requires significant time and effort. Medtronic Core Valve's US Pivotal Trial for patients at Extreme or High-Risk for surgical aortic valve replacement was conducted in 45 hospital sites in the United States.

6.

[redacted]

7. [redacted]

8. [redacted]

9. CMS requires TAVR-authorized heart teams and hospitals to participate in a national registry that tracks patient outcomes following TAVR procedures. That registry "accepts all manufactured devices."[2] Accordingly, there is no reason a TAVR-authorized hospital cannot have heart teams trained in implantation of both the CoreValve THV device and the SAPIEN THV device. [redacted]

[2] http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&ver=1.

[redacted][3]

10. Edwards has publicly stated that it thinks SAPIEN is the "default strategy" for TAVR clinicians and that physicians' existing experience with SAPIEN will be "a factor going forward" in their choice of which TAVR product to use. **Exhibit B** at 26-27.

11. Edwards most recently publicly reported that it has sold SAPIEN THV to 284 of the approximately 350-400 TAVR-qualified sites trained in implantation of the SAPIEN THV and that it plans to add 45 to 65 sites by next year. **Exhibit B** at 6. [redacted]

12. [redacted] I understand that Edwards similarly priced the SAPIEN THV significantly lower for its clinical trials, charging approximately $25,000 per device during its US clinical trials. I

[3] "But the long-term growth is really going to be driven by our existing sites, which are the larger centers. And it's going to be driven by increased awareness. It's going to be driven by referral barriers changing and decreasing; and improved economics of the centers, which is going to be driven by their experience as well as new technology." **Exhibit B** at 6.

understand from reviewing a research report prepared by a third party that Edwards charges approximately $32,500 per commercial device in the US.

13. I understand from public statements made by Edwards that in countries where the SAPIENT XT THV is sold commercially, Edwards quickly discontinued the SAPIEN THV once the SAPIENT XT THV was available for purchase. I further understand that Edwards intends to similarly discontinue SAPIEN THV in the United States once the SAPIENT XT THV is commercially available. *See* **Exhibit C, Exhibit D**, **Exhibit E, and Exhibit B** hereto.[4][5][6][7] Edwards anticipates that SAPIEN XT will be approved "in the first half of next year." **Exhibit B** at 6. I understand that Edwards sells the SAPIEN XT THV in Europe for 10 percent more than the price of the SAPIEN THV.

14. Edwards recently publicly stated that it expects its newest TAVR product, the Sapien 3, to become commercially available in the United States by 2016. **Exhibit B** at 9.

15. Edwards recently publicly stated that "the U.S. has ramped a little slower than what we would have originally anticipated but we think this opportunity remains very robust and we see a lot of growth in the future." **Exhibit B** at 5.

//

//

//

---

[4] In the words of Larry Wood, the Corporate Vice President responsible for Edwards' Transcatheter Heart Valves, "[W]e know from our European launch the conversion from SAPIEN to XT went very, very quickly. I think we converted almost all of our transfemoral customers within really a matter of a couple of months. . . . I think once we get the XT approval, I think we'll be able to move very, very quickly to convert all of our customers." **Exhibit C** at 3.

[5] In the words of Tom Abate, the CFO of Edwards: "[O]ur goal is to get everything that we can outside the US to XT, including the US. So it will give us some efficiencies. . . . [B]eing able to drop SAPIEN should help." **Exhibit D** at 15.

[6] Larry Wood confirmed this week that the transition to XT in the US will be "rapid and seamless." **Exhibit E** at 17.

[7] Larry Wood further stated that "to convert a customer from SAPIEN to XT goes very, very quickly. It doesn't require new simulation. It doesn't require intensive training." **Exhibit B** at 9.

I declare under penalty of perjury that the foregoing is true and correct. Executed on December 12, 2013, in New York, NY

Rhonda Robb

RHONDA ROBB

EXHIBIT A

REDACTED IN FULL

EXHIBIT B

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

EW - Edwards Lifesciences Annual Investor Conference

EVENT DATE/TIME: DECEMBER 09, 2013 / 1:30PM GMT

CORPORATE PARTICIPANTS

David Erickson *Edwards Lifesciences Corporation - VP, IR*

Mike Mussallem *Edwards Lifesciences Corporation - Chairman, CEO*

Larry Wood *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Markus Kasel *Edwards Lifesciences Corporation - Proctor*

Don Bobo *Edwards Lifesciences Corporation - Corporate VP, Heart Valve Therapy*

Carlyn Solomon *Edwards Lifesciences Corporation - Corporate Vice President, Critical Care and Vascular*

Tom Abate *Edwards Lifesciences Corporation - Corporate VP and CFO*

CONFERENCE CALL PARTICIPANTS

Amit Bhalla *Citigroup - Analyst*

Rick Wise *Stifel Nicolaus - Analyst*

David Lewis *Morgan Stanley - Analyst*

David Roman *Goldman Sachs - Analyst*

Glenn Navarro *RBC Capital Markets - Analyst*

Mike Weinstein *JPMorgan - Analyst*

Larry Biegelsen *Wells Fargo Securities - Analyst*

Bruce Nudell *Credit Suisse - Analyst*

Bob Hopkins *BofA Merrill Lynch - Analyst*

Michael Mack *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

Brooks West *Piper Jaffray & Co. - Analyst*

Samin K. Sharma *Mount Sinai Medical Center - Director of Clinical Cardiology and President of the Mount Sinai Heart Network*

Joanne Wuensch *BMO Capital Markets - Analyst*

Raj Denhoy *Jefferies - Analyst*

Kristen Stewart *Deutsche Bank - Analyst*

Randy Martin *Piedmont Hospital - Chief of Valvular & Structural Heart Disease*

Wes Pedersen *Minneapolis Heart Institute/Abbott Northwestern Hospital - Interventional Cardiologist*

PRESENTATION

David Erickson *- Edwards Lifesciences Corporation - VP, IR*

Good morning. I'm David Erickson, Vice President of Investor Relations for Edwards Lifesciences. I would like to welcome you to our 2013 Investor Conference. Before we get started, I would like to go over a few housekeeping items. This morning we issued a press release that summarizes the information we will be discussing today, and a copy of this release was placed on the tables in front of you and is also available on our website.

Today's conference is being webcast live. A replay of this event and copies of the slides presented today will be available on our website as soon as possible after the conclusion. During Q&A times, so that everyone in the room can hear, as well as for the benefit of those persons joining us via

the live webcast -- if you have a question, please raise your hand, and we will bring you a microphone. Please identify yourself before asking your question. And also please limit the number of questions that you ask, so that we can get to as many people as possible.

Following the conference, you will receive a short electronic survey. We would greatly appreciate receiving your feedback on today's event.

During today's conference, Edwards management will be making a number of forward-looking statements. These statements speak only as of the date on which they are made, and we do not undertake any obligation to update them after today. For more information about the risks associated with these forward-looking statements, please refer to the forward-looking statement included at the bottom of today's press release and in documents filed with the SEC that are available on our website.

Today's presentations include figures identified as underlying and excluding special items. When we use these terms, we are referring to non-GAAP financial measures. Otherwise, we are referring to GAAP figures. A reconciliation of non-GAAP measures is included in your handout, and is also available on our website.

In the interest of full disclosure, these are the relationships and the financial arrangements that pertain to the clinicians that you will be hearing from today.

And with that, I will turn things over to Edwards' Chairman and CEO, Mike Mussallem. Mike?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Good morning, and welcome. Thank you very much for joining us today. Whether you are on the webcast or with us live, we appreciate your interest in Edwards Lifesciences. And we've have got quite an agenda to walk you through today. And I look forward to sharing a lot of information about where we are today; what the prospects are for 2014, and well beyond.

So just to jump into it, Edwards has a very clear strategy. We are a global leader in what we do. We think companies like us add the most value for patients, for physicians, and for investors, when we truly innovate patient care. That's what we are focused on. We are able to manage those risks by staying close to home in fields that we understand. And we are fortunate to be the leader in structural heart disease in clinical care, and proud to say that over 95% of what Edwards sells is in a number-one global market position.

We also actively manage our portfolio. We move away from things that we don't think are valued and have bright growth prospects. And we try to move into areas that are particularly attractive. We think there's some really interesting opportunities across the board for Edwards, but particularly in structural heart disease, where we think there's opportunities to add additional growth.

We manage our Company by strategic imperatives. We have four simple strategic imperatives in place today -- to lead the global transformation of aortic valve disease treatment; to lead the development of transcatheter mitral valve replacement therapies; to drive acute-care monitoring to the standard of care for appropriate patients; and to strengthen our processes to support growth and improve profitability.

Everything we do is really focused on these imperatives. We put detailed goals, detailed measures. This is where our energy goes. This is where our investment goes. We measure this routinely and in a detailed fashion. And we reward our management team and our employees based on our attainment of these goals.

Now, just to reflect on the environment, and what might have changed since we were here a year ago -- on a macro basis, there's a growing influence of the economic buyer. Physicians continue to be very important, and the most important person in the choice of Edwards' products. But the economic buyer has a growing influence. And they are more and more interested in clinical evidence and cost accountability. The regulatory environment is also evolving, sometimes kind of slowly. But we feel like, both in the US and in Japan, there's a commitment to allowing beneficial therapies to come to patients faster. And we see favorable movement.

Conversely, in the EU, we think they are becoming more rigorous in their regulatory processes. And then we are encouraged to see that the economy in Europe, we think, is stabilizing for a number of reasons. The competitive landscape is changing pretty rapidly. We see a transcatheter heart valve strategic competitor much closer to the US in Europe. Our patent litigation is ongoing; largely very favorable for our Company. We find competitors less focused on surgical valve innovations; we find it quite remarkable. And no dramatic change in the competitive environment in critical care.

So when we reflect on what we think 2013 is going to look like when the books are finally closed, we expect it to be considered a solid year with underlying total sales growth of around 10% for our Company. Our US THV sales were strong, but they were certainly below our original guidance. Our US annual sales growth in THV, we estimate, will finish in the 45% to 50% growth range. And that affected our global annual growth range for THV, probably settled in the 25% to 30% range, where we had previously estimated that it would be in excess of 30%.

During that period, we maintained focus on durable long-term success. We have had major advancements in our important new platforms that we are able to bring to each geography around the world. You are going to hear more about that. And I am very pleased that our clinical evidence has continued to get stronger and stronger. And this is really the foundation of what we do. And having that clinical evidence get stronger all the time is an underpinning of our long-term success.

And finally, I am proud to say that in each of our major product lines, Edwards gained market share during the year. Tom Abate is going to talk to you later about reconfirming our October 13 guidance at this point in time.

Now, as we turn the page to 2014, it is going to become a very interesting year, probably more challenging from a growth perspective than we have encountered in the past. We will stay focused on the long-term, but we have new THV competition, particularly in the US. We are expecting an early entree from competition. There is a fair amount of uncertainty in the year. Because depending when competitors are approved and our own products are approved, for example, in the US, it drives a relatively wide range of possibilities. So predicting this precisely is a little difficult right now. We will provide more clarity as the year goes on.

We also have two new strategic competitors in Europe. You can count on the fact that Edwards plans to aggressively respond to this THV competition. We will meet force with force. One of the things that you should expect from us is that we plan to upgrade to our next-generation technologies, and do that at current prices. That will put some pressure on our gross margins in the near-term, but we think that's the way that we build long-term value. We are also making increasing investments in our customer-facing organizations. And we think that that is probably more valuable in 2014 than ever. We also expect very solid performance from our base businesses in 2014.

Now, when you think about 2014 and beyond, even though we have estimates that we think are quite reasonable, there are true upsides that are not in our plan. Success in transcatheter mitral valves, and driving leadership there, is not in our plans; nor are new structural heart or glucose innovations. We think there's an opportunity for clinical evidence to continually distinguish us from our competitors. And you know we are collecting an awful lot of new clinical evidence. Although we think our approval dates are estimated fairly, there is an opportunity for them to come earlier. There is a potential for greater operating leverage. Strong cash flows are in our future, which will enable us to have more strategic flexibility. And we think it is likely that we will have an upside from IP litigation, but that is also not in our plans.

One of the things that Edwards has been steadfast in is our investment in our pipeline. And that pipeline is a rich one, and we think that affords us multiple opportunities to create long-term value. You will hear about many of those, in far greater level of specifics, during the course of the day.

So just to walk through what to expect here at the conference, Larry Wood is going to kick off and talk about how we expect to extend our leadership program in transcatheter heart valves. Markus Kasel is joining us; he is a leading interventional cardiologist in Germany with a tremendous amount of TAVR experience, and also a proctor in the US and around the world.

We have got an incredible panel to talk about transcatheter heart valves that are US-based -- Michael Mack, Steve Ramee, and Dr. Sharma are all respected leaders with very distinctive and unique points of view. Each will be individual, and I think that you won't find them afraid to share exactly how they feel.

Don Bobo will talk about expanding surgical valve opportunities. And then we will have a particular focus, or a clinician panel that's focused on mitral valve treatments and the evolution of that. Some true experts in the field that can talk about how mitral valve disease is treated -- or not treated -- today, and how it might be treated in the future. And it's really a remarkable panel. Carlyn Solomon will talk about our advances in critical care. Tom Abate will talk about our financial outlook, with a particular focus on 2014. And I'll make some closing remarks reflecting on the future beyond 2014.

Also in our audience today are some other members of our executive leadership team which include Dirksen Lehman, Stan Rowe, and Aimee Weisner. And I am also pleased that Scott Ullem, our incoming Chief Financial Officer who will be beginning the first of 2014, is also with us. Scott, where are you? Would you stand up? You can see Scott -- for those of you in the audience that would like to meet Scott and say hello, I think he would welcome that.

So, at this point, I would like to introduce Larry Wood to talk to you about transcatheter heart valves.

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Okay, thanks, Mike. It's always a pleasure to talk to you guys and provide an update on transcatheter heart valves. So I will jump right in. One of the things that we are very proud of is the number of countries we can now service with our transcatheter valve platform. We're approved, and offer this for patients now, in over 60 countries. When we look at the transcatheter valve opportunity, I think everyone is aware that the US has ramped a little slower than what we would have originally anticipated. But we think this opportunity remains very robust, and we see a lot of growth in the future. When we look at the total market now, we now estimate this to be a $2 5 billion to $3 billion opportunity by 2019. And we see, still, a lot of growth and a lot of opportunity in this marketplace.

One of the questions that we get a lot is about the undertreatment of aortic stenosis. So this is a slide that we have used before. We used it last year, and we talked about the number of patients with severe symptomatic aortic stenosis who don't get therapy in this country. So when we look at that whole pool of patients, only about a quarter of patients with severe systematic AS get treated today.

We also went through some of the reasons why patients don't get treated. And these patients, a lot of them, are in the hospital. They have had an echo; they have been diagnosed. But for whatever reason, they don't end up going for therapy. And there's a lot of reasons listed here, and this is some of the work done by David Bach. But a lot of times, it's just because they have higher risk. They have a lot of comorbidities. So they are not technically inoperable. But for whatever reason, they don't move forward for therapy. And these are the patients that we think the availability of transcatheter valves really have the opportunity to serve.

So we get a lot of questions about whether these people will really come off of the sidelines and pursue therapy. And so we wanted to try to answer that question more directly. We went back and looked at Germany, and looked at the first three years of launch. And what we looked at is the growth rate of aortic valve replacement procedures has grown about 13% annually. And that's surgical aortic valve replacement as well as transcatheter aortic valve replacement. When we look out, though, in seven years in Germany we have seen a doubling of the number of patients who have received aortic valve replacement. Now, one of the questions we get a lot is whether these are patients that would have otherwise gotten surgery that are now simply being converted to transcatheter valve patients. But that's not what the data suggests.

What we see is the growth in the market has largely been driven by transcatheter heart valves. But surgery has remained flat during this period of time. Now, I think you could say that if transcatheter valves didn't exist, surgery would probably would have grown at its historic rate of 2% or 3%. But clearly, the growth in Germany has been led by the availability of transcatheter heart valves.

Now, we compare this to the first three years in the US experience -- and admittedly, Germany isn't probably a perfect analog for the US. But we think it's a good analog. They are both sophisticated healthcare systems, and they have stable reimbursement across. And when you look at the first three years in the US, we see about a 12% annual growth rate, so very similar to what we saw in Germany. And very similarly as well, while transcatheter valves drove the growth, we didn't see a decline in surgery. Surgery still grew about 1%. So we think this is very encouraging for what the future of transcatheter heart valves is in the United States.

Long-term, we think it can still expand dramatically. It's important to remember that only the sickest patients today have the opportunity to receive transcatheter heart valves in the United States. A successful PARTNER II trial, continued good data -- and you know, we've studied these out extensively. We have our registries that are ongoing in Europe. We have our randomized trials that are going forward in the US. And the data continues to hold up extremely well. And as that data continues to look good, and we get longer-term outcomes, we think it's going to lead to further adoption of this therapy.

Longer-term, we look at moderate and lower-risk patients. Younger patients are often under-diagnosed or they delay their treatment. And we just know that the devices are getting better; the skills, the techniques of the clinicians are getting better. And the rapid recovery and the quality of life benefits, we think, could encourage earlier treatment. So we are very excited about the long-term prospects of transcatheter valves.

Turning our focus to the US, I think everyone is aware of our portfolio here. We currently sell SAPIEN. We expect to have SAPIEN XT approved in the first half of next year. And then we have our SAPIEN III valve, which is enrolling in a clinical trial.

We have now, as of today, about 284 commercial sites. And last year, when we talked about how many sites we would add, we said that we would add about 100 centers in 2013, and we would add probably another 100 centers in 2014. We are not too far off that pace, being at 284 for right now, today. And we will probably add a couple more before the end of the year, so we are not too far off that. But next year, we see, we will probably add less centers than what we had originally projected. We see that we will probably add 45 to 65 sites. And the reason for that is the national coverage decision, I think, has just turned out to be a little bit more restrictive than, I think, what anyone would have anticipated when it was originally written.

But the long-term growth is really going to be driven by our existing sites, which are the larger centers. And it's going to be driven by increased awareness. It's going to be driven by referral barriers changing and decreasing; and improved economics of the centers, which is going to be driven by their experience as well as new technology.

Now, when we look at reported sales year-over-year, we had about a 45% to 50% growth in reported sales. And these are our estimates based on where we are today. Maybe a better way to look at the health of our businesses is looking at what happened with reorder sales. So remember, every site, when they started to get a stocking order -- and that is influencing our reported sales. But when we look at reorder sales, which we think is a good surrogate for actual procedure growth, we projected we will have almost an 80% or about an 80% increase in the number of procedures. So, while it hasn't maybe grown as fast as we thought, it's pretty robust growth to have an 80% increase in procedures year-over-year.

When we go back and we think about the launch, there was a lot of questions about whether transcatheter heart valves could be launched effectively in the US. I think the FTS and the ACC really advocated for what they called rational dispersion. And they really want us to be thoughtful about the rate in which we trained centers, and who actually got access to this therapy.

And I think there were really three key questions. One of the questions was, could these clinical trial results be duplicated outside of this controlled clinical trial? Remember, in the clinical trial, we had really the elite cardiac centers in the world participating. And there was a lot of questions about whether this could be generalizable outside of that elite group of physicians. Would there be risk creep? There has been examples of other technologies that were studied in a fairly narrow population, but once they were approved they went off-indication, and so there was concern about risk creep.

And I think just the concept of the heart team -- would the heart team be durable with surgeons and interventional cardiologists working together? And the answer to really address these questions was the creation of a national TVT registry to track outcomes in the commercial setting.

So this data came out and was published recently. And I'll tell you, we couldn't be more proud of this data. When we look at this, and we look at all the challenges and concerns that people had about the launch, we think this represents probably one of the best launches that has ever occurred in medical devices.

There's a lot of interesting points in this data itself, though. One of the things that we saw was actually the breakdown of inoperable patients to high-risk patients. And we see only about 20% of the patients were deemed technically interoperable. So 80% of the patients who received a

transcatheter heart valve were deemed as being high-risk. So it means they weren't -- it wasn't that surgery wasn't an option for them. But for whatever reason, surgery was just deemed not a good option. And these were patients that now pursued having their aortic valve replaced.

One of the other things is we saw a dramatic increase in the number of centers that offer this therapy. So we went from 25 centers to 250 centers who now offer this therapy. When we look age, and this concern about whether this was going into lower-risk or younger patients, we use age is a good surrogate. And what we see here is there's not really any suggestion that the patients got younger, with the ages for the inoperable cohort being the same. And we actually saw a slight increase in age for the high-risk patients. And I think this just reflects a lot of the patients that are out there that are in their 80s. They are frail. They are not inoperable, but they are high-risk. And for whatever reason, undergoing an invasive surgical procedure is just not something that they are interested in doing. And I think that this is one of the things that we see here is that we have stayed very, very well on-indication.

But the thing that we are most proud of is the outcomes for patients. We've always said that our focus for this launch was going to be maintaining procedural success and really focusing on outcome. And that's what we built our whole training program around. It's what we built our whole proctoring program around. It's making sure that we delivered spectacular results for patients. And when we look at these [8 and 2] and in all the sites that reported in the TVT registry, we see that the mortality results are very comparable to what was done in the clinical trial sites. I think -- we didn't analyze these statistically. But I can say pretty assuredly that these would not be statistically significantly different.

And when we look at the reported stroke rates -- which obviously don't have the same scrutiny as they did in the clinical trial -- but you look at the reported stroke rates and they are pretty impressive. So we are very, very pleased with how this has gone. We are very pleased with how the launch has gone. And the fundamentals, we believe, for the long-term success of this was making sure we are doing great things for patients. And I think we can check that box and say that we did a good job.

Bob Bonow, who is one of the world-renowned experts in this -- he is very influential and does most of the guideline writing in this space. I won't read his whole quote here; it's in your book. But he really highlighted these excellent clinical results and the success of this rollout, and the unique collaboration that happened between industry and societies and regulatory agencies to ensure that patients received safe and effective care. And again, we are very proud of how this has gone.

And when we launched this therapy, our focus was on procedural success. So what that means is we really focused on the screening of patients; the imaging; and then the procedure itself in the cath lab with a hybrid suite. And that's where we spent all of our time and all of our energy. As we trained over 250 centers, now, we are switching the focus of our training team to look at areas outside of just the procedural aspects. So one of the things that we do is we try to raise awareness about the procedure.

We do what we call therapy awareness dinners, where we take teams from our TAVR centers, we reach out in the local community. We will host dinners or we'll host events where they can reach out to the clinically based cardiologists; make sure that they are, one, aware of the therapy, that they are aware of that outcomes; but also just that they know what types of patients are well-suited for this procedure; and, maybe even most importantly, where to send those patients so that they can get evaluated for transcatheter valves.

We also look, though, to what happens to the patients after the procedure. We are starting to increase our focus on length of stay, and how centers can be optimized. What we really try to do is share best practices across sites so that that they can make improvements in these areas which had impact, not only to patient care and improving that, but also had impact to their economics by looking at things such as length of stay and appropriate discharge planning.

Now, when we started the PARTNER trial, and in the early experience here, we spent no energy and there was no focus on reducing length of stay. We were focused on one thing, which was making sure we drove great outcomes. In spite of that, we have seen a slight decline in length of stay, from eight days in the PARTNER trial, to seven days in the first report from the MedPAR data, down to six days in the TVT registry. We believe with increased focus on this, which is really just starting now, that we can see significant reductions in length of stay, and that these can decline. And again, when you look at the economics for the hospital, and ICU day costs in the neighborhood of about $3000, and a day on the general award cost about $2000. So these are very meaningful reductions in cost for the hospital when we can take out length of stay.

Now, here is one example where the team has really focused on this. And this was reported by Dr. David Wood, who is with John Webb's group in Vancouver. And Vancouver is a very experienced center. They have been working on TAVR from really the very beginning. And they just recently started focusing on how they could reduce their length of stay and really run a different protocol.

And what they really focused on is minimizing the procedure, screening patients very carefully, but then also early mobilization of these patients. And what they showed -- and this was all done with our safety and efficacy platform -- that they had a mortality at 30 days of 1.6%, which is incredibly low. Their median length of stay was one day. And in fact, 65% of their patients were discharged one day post-TAVR, and their mean length of stay was about 1.67 days. So I don't know that this is something that every center is going to be able to do, but it certainly highlights the potential of this therapy to offer very low length of stays for patients, which I think highlights the short recovery time of having a good TAVR procedure.

Turning our focus to Europe, right now our commercial offering is our SAPIEN XT valve. Our SAPIEN III valve, we expect to be approved right about the end of the year. And we are also enrolling our self-expanding CENTERA valve in a clinical trial.

Now, Europe -- we are well into the launch in Europe. But it continues to grow very significantly. And when we look at 2010 to our estimates in 2013, we have a CAGR of about 19%, which is pretty incredible when you consider how fast this has grown and how many of these procedures are being performed now. When we launched SAPIEN in Europe, we split the market pretty evenly with our competitor. We had about 50% market share. But when we look at transfemoral and alternative access, we only had about 25% share in the transfemoral space. And we had almost all of this year in the alternative access, which was primarily just transapical.

And that was really driven by the profile of the devices. SAPIEN is a 22-24 French system, and our competitor is an 18 French system. When we launched SAPIEN XT, though, we gained significant transfemoral share. We now believe we have over 50% of the market in Europe. We also believe we are the transfemoral leader. While there has been new competition in the alternative access space, we still are clearly the market leader in alternative access. And this is really reflective of getting down to a competitive profile. And we think the future looks very, very bright.

Having our SAPIEN III valve -- which we think is unique, and I will talk about a little bit more later -- having a 14 French profile, we think this competes very, very well with any new platforms that are going to show up in the near-term horizon.

In Japan we have launched SAPIEN XT, and that launch continues. One of the areas of focus for Japan is actually moving -- or is adding the 20-millimeter valve. This is a valve that was really designed for the Japanese market. We have completed the trial on that, and we will look to add that into the commercial offering. We think the Japan opportunity is very, very attractive. While the launch is going at a measured fashion, and it is being gated really by the site certification process, so the site has to be certified by the medical societies. And they just have a capacity to do about four sites per month. But the reimbursement is very good, at $46,000, so very good pricing that we get in Japan.

But the other thing that we see is the market characteristics are very positive. The ratio of stents to CABG surgery is much higher in Japan that it is in pretty much any other region. We know that aortic valve replacement is undertreated there, and they have a larger population of patients over the age of 80. So we see this is a $300 million to $400 million market by 2019.

Turning to pipeline, I will start with our SAPIEN III valve. We could not be more excited about this valve than we are. This is a unique product. I think one of the things that is really great about it is it's an extremely low profile. It is delivered through a 14 French eSheath. The other thing, though, that we are really excited about is its ability to further reduce paravalvular leak. So we have a very unique skirt, cuff, on this device. And our early experience shows a pretty dramatic reduction in paravalvular leak. So we are very excited about the potential for that.

The other thing, though, is it really builds on our SAPIEN and our SAPIEN XT platforms. There is nothing really terribly different about it. The implant procedure itself is very similar. It's something that we can teach people and convert people very quickly. And the other thing, too, is we didn't make any compromises on valve durability. It uses our same treated bovine pericardial tissue that we use in our SAPIEN and in our XT platforms.

The last comment on profile, though -- everybody talks about profile a lot, for what it means for the transfemoral procedure. But we also believe reduced profile is going to be really important for alternative access. And with SAPIEN III we can get down to an 18 French profile for our alternative access approaches as well.

When we look at the timelines, SAPIEN XT, as I said -- we expect to get that in the first half of 2014. We have moderate-risk patients; this is our PARTNER II trial. We've completed enrollment in that. That trial has a two-year end point, so we estimate it getting approval with the expanded indication in 2016. The SAPIEN III -- we are enrolling that trial now. Enrollment in that trial is going quite well. That has a one-year follow-up, so we also see SAPIEN III being available in the US market probably in the 2016 timeframe.

CENTERA -- we haven't talked as much about CENTERA, so it's a great opportunity to tell you why we are excited about CENTERA and its potential. CENTERA is probably the most advanced transcatheter heart valve that has ever been developed. It has a lot of unique characteristics. It's a self-expanding valve but it's a short, discrete frame, similar to our SAPIEN product lines. The way that we position accurately a short self-expanding frame is we have created a very novel motorized delivery system which helps us deploy the valve very stably, very precisely, where we would like it. Because it is a motorized system, it allows for a single operator use. It also goes through a 14 French eSheath. And this has our most advanced GLX-treated bovine pericardial tissue. So we will resume in a moment with our commercial version of this system, and we expect to have this approved in Europe in the mid-2015 timeframe.

So I will show you a short video here, but this is one of the reasons why this system is so cool. The system will be delivered just like this, in a package. To prep the system, rather than use a crimper, or rather than use a cold water bath, all you have to do is hook the motor drive up; flush the system; take the motor, push the reverse button. The valve is drawn back into the delivery system. And you take the motor off, and the system is ready to be implanted. So, very quick, very efficient. Really best-in-class ease-of-use for system preparation. And again, we think this will really facilitate single operators and improving efficiencies in centers.

So one of the things that is critical to our overall strategy is making sure that we have a robust pipeline, and that we continue to focus on innovation in this space. And what we are really trying to make sure we are doing is meaningful innovation. We are trying to advance this and improve the patient experience as well as improve the physician experience. And so you can see we have major product launches planned across all regions over the plan period. And this is really the cornerstone of our leadership strategy, is making sure we are always leading with best technology.

So, today, we are very well positioned to compete really with anybody in any geography. Our SAPIEN platform has the most robust clinical data. It's the only product with four New England Journal of Medicine publications. We have very low 30-day mortality rates, very low pacemaker rates. Our SAPIEN XT platform -- it's the only one to offer a combination of our treated bovine pericardial tissue -- the same tissue we use in our market-leading surgical valves -- as well as a 16 French eSheath. And because these technologies are very similar, to convert a customer from SAPIEN to XT goes very, very quickly. It doesn't require a new simulation. It doesn't require extensive training. We can do that just at the hospital.

And that's true of SAPIEN III as well. So when we convert customers from XT to SAPIEN III, we expect it to go very quick. We will make these conversions very easy for customers. We are not going to go for significant price increases. We are really just going to try to move people to these platforms at basically the same comparable pricing. And most of these products are going to be under consignment, so we think we can facilitate a rapid improvement. And we think that's going to be really embraced by our customers.

So our model for 2014 is fairly complicated. I will walk through a lot of the things that we put in the model, just so you know how we factor these things in, and how you can apply them to your own model. So we have anticipated that a US competitor will enter the market very early in 2014 within an extreme risk, which is similar to a non-operable indication, and that their high-risk indication comes in Q3.

We expect the approval of SAPIEN III to happen within a few months of the competitor's extreme risk indication. We are expecting our competitor to be very aggressive with site activation. We expect them to move very quickly into centers. One of the things that we are doing to counter that is we are accelerating our conversion of customers to consignment. It's just one thing that we can do to partner with sites and drive loyalty and build on the relationship, is by helping to convert them to consignment. But what that means is is the net stocking reduction, as we convert people to consignment, will reduce our reported sales by about $20 million to $30 million in 2014.

In Europe, we have the full impact of two strategic competitors, but we'll also have the full impact of SAPIEN III. And again, we will move aggressively to upgrade customers to our new platforms. In Japan, we estimate sales of $40 million to $50 million. And, overall, we expect pricing to remain pretty stable, with just modest volume discounts for centers that do high volume.

So, 2014 is a challenging growth year. We expect, overall, the global market to grow about 20% to 30%. We have new platforms. We have SAPIEN XT in Japan. We have SAPIEN XT that will be coming in the US, and we have SAPIEN III in Europe. But we also have new competition. We have new competitors in Europe, and we have a new competitor in the US. And we also have competitive clinical trials. So we estimate our global sales to be about $700 million to $820 million.

But when we look out beyond -- when we look past 2014, and we look to 2015 to 2019 -- we see this as being a great opportunity and a real return to growth for us. We expect this market to grow about 15% to 20% annually. We think the market will continue to develop. We think referral patterns begin to change; therapy awareness increases. We expect having expanded indications. We will have our new platforms. And we will continue to launch our next-generation technology. And in the US, we don't expect a third competitor for quite some time. We expect there will be new competition in Europe and Japan, but we believe that our pipeline is really what enables a durable leadership position.

So with that, I would like to introduce Dr. Markus Kasel. He is a real expert in the transcatheter valve field. He was one of the early adopters in Europe. I think you will like to hear his experience, and how those have changed over time. He is a highly sought-after proctor and does a lot of proctoring for us and for others as well. But he is also a very busy practicing interventionalist. He himself will personally do in the neighborhood of 300 transcatheter valve procedures this year.

So we're very proud to have Markus here. Markus?

Markus Kasel - *Edwards Lifesciences Corporation - Proctor*

Thank you for invitation. So, my name is Markus Kasel. I work mainly in this hospital; it's the German Heart Center, and close to the center of Munich. I was asked to talk about my TAVR history. So here is my history.

I started in this hospital, Klinikum Bogenhausen. It is one of [communal], big communal hospitals in Munich. And there I started 2007, together with a colleague from [Ishinga] TAVR program. And at this time, we have chosen the Medtronic CoreValve device because it was available with 18 French sheath. It was possible to implant this valve over 18 French sheath.

And so in the following two years, we did around about 120 successful implantations with this device. So, 2009, there was a change in my hospital. A new head of the protocol department came and he asked me to try a different valve. It was SAPIEN valve, because his opinion was, it looks more like a surgical valve, and perhaps it has an impact of durability and form.

And so we started then with transapical implantation. And we did in the following two years round about 50%-50% transapical and CoreValve implantations. So 2010, then, the SAPIEN XT device came onto market. And so SAPIEN XT was also implantable over a smaller sheath. And so we had then, at this time, our experience with transapical safe environment, it shows in comparison to the CoreValve device some good points like lower pacemaker rate; and also, in my opinion, lower (inaudible) rate.

So we started then, in 2010, with the SAPIEN XT device, transfemoral. And, so again, two years, and we did around about 150 implants a year. And at this time, when we had SAPIEN XT, it was two-thirds SAPIEN via transfemoral access, and one-third via transapical access.

At the same time, I became Proctor for SAPIEN and also for the CoreValve device. And then in 2011, I changed my working place. I changed to the German Heart Center, where I worked mainly. And also I changed to the Klinikum Augsburg. The German Heart Center -- they were experienced. They had a TAVR team. It was driven by the surgeons there. And so we, all together in the following years, two years, again we reached 6000 heart implants at the end of 2012. And we celebrated the 6000th heart implant in April of this year.

And in this year all centers are -- and the second center, where I work -- I forgot it -- is the Klinikum Augsburg. This is a big communal hospital 62 meters south of Munich. And I worked there only one day a week? And every Tuesday, we do three TAVR valve implants there. And also this center was this year very busy with 150 valve implants. And in the German Heart Center we did, in two teams, more than 300 valves this year.

And me, I choose -- my working hours at the moment is the SAPIEN XT. I do more than 80% of implants, I use this valve. And perhaps 15%, or less than 15%, I use self-expanding valves, mainly CoreValves for patients, for example, with special issues like too big annulus, too small annulus, perhaps the calcified [ultra for protect].

So I want to talk about these five critical points for TAVR which influence my choice of valve. So I want to start with procedure safety. Here I want to talk about implantation techniques, and also about access way, because most implants the safety of the device.

So let's start with implantation of a SAPIEN valve. So the main step here is -- or key step is to have a good implantation view, as you see here. It's a catheter here in the right cuff. It's about 3 cuffs, and the main thing is that you bring all 3 cuffs in one line. And once you have the three cuffs in one line, you have a good landing place for your valve.

And then, next step, so we published an easy way to get to a good implantation view at the beginning of this year. so you could do this easily with the help of a fluoroscopy wire procedure. So here is an implantation of a SAPIEN valve. So we give contrast. We see that anatomic situation. We open the valve slowly, and we place it really precisely good place of our valve. We replace [a presize] it's a good place. Here, when you look there at next group once again, so here we give contrast. We adjust the valve. I've pushed it a bit down. And then we deploy it 40% toward and 60% towards the other. And this the sight -- what we see is very often valve is in a good place and another -- so here, in this case, no insufficiency.

So here is comparisons. The CoreValve is a valve -- the deployment of this valve is completely different. So you have a lot of steps, and you need -- for these steps you need more contrast. It's a step-wise deployment, and we use a lot of time not rapid pacing; we use slow pacing. It is possible to place, also, this valve at a good place. But it is not every time really predictable where it lands. Because the final step, when you release the valve, it makes a final turn. And this turn is not, every time, really predictable.

If you misplace the valve and it is anchored at the system, you could pull it back. But it's -- or you could recapture it. But it's not really a recapture; you pull the open valve back through the arch and then you could start again.

So second thing what has to do with safety is the TAVR access. We have a lot of surgical access ways. And we, as the cardiologists -- we have the transfemoral puncture technique. But I think this is, in my opinion, when the choice is good, the safest way to implant the valve.

So our decision is also transfemoral at first. So we do every valve which is possible to implant via transfemoral access. We do this implant transfemorally. And so with the current devices, two-thirds of our implants are possible over the transvascular access way. So, in the future, with new developments, we get smaller sheath. And I think this relation will go more -- again, more towards a transfemoral approach.

So the main topic is paravalvular leak, because paravalvular leak influence the patients' outcomes a lot. So one main point for the SAPIEN valve -- it's a good patient screening or good patient preparation. And here is chart published also in this year to choose, really, the right valve size. And so this is mainly in our hospital, based on CT measurement where we measure the annulus of the valve. This is the place where the valve would anchor. And depending on our measurements, we choose the correct valve size.

And this has really a big impact on the success, because when you choose the two big valves, and you make oversizing, you will see severe complications like annular ruptures. And when you choose a too-small valve, then you see a lot of paravalvular leaks.

So, when I compared both valves, I think for balloon expandable valves like the SAPIEN, a precise measurement of the annulus and the choice of an optimal valve size is mandatory. The reason is the radial force of the balloon expandable valve are much higher. And the valve itself modifies when you implant the valve into the anatomic obstruction to the annulus; it modifies the annulus shape. It makes it round like a surgical valve. And so the oversizing range is very limited.

Self-expanding valves, in contrast, adapt more to the annular shape. And they have a much bigger oversizing range, so it doesn't matter when you take a too-big valve.

So as I told you, my opinion and my observation is that we see less paravalvular leak with the SAPIEN system when the measurement was good before. And this is also shown in a lot of registries.

Next point, pacemaker rate -- here is the difference clear. We see a lot of more pacemaker implants in the good CoreValve systems, in comparison to the SAPIEN system. The reason is you have a much higher valve frame. And this valve frame could interfere, or touch the conduction system and the upper LD outflow tract. And this could make a blockage of your heart rhythm.

So here, only for your understanding -- so the SAPIEN valve really needs only a small place. It replaces the native valve at its place. It's an intra-annular concept. CoreValve valve is anchored -- it's a much higher frame. It is anchored also in the ascending aorta.

So as I told you, we have seen a lot of more -- we have to implant more pacemakers with the CoreValve device. And what we did from the beginning on, we tried to implant the valve higher, to the point that it touched the upper [ultral] plate. But as you see here also, when you implant the valve higher, then it covers more of the coronary ostia. And one main point is that the later access to the coronal arteries is sometimes really changed are not possible.

Next point, stroke rate -- I think the latest data have similar comparable stroke rates for both sized valves. So we use in our center at the moment, or we look or we implant valves. Also it's under [xenograft] protection, but there is discussions at the moment [controverse]. And we don't know at the moment, really, if you could protect the patient with these devices from stroke.

So my last point is durability. And so I want to show how these two different valve platforms or valve types perform in the patient. So, here, if I think the typical implantation of the CT, after implantation of a typical CoreValve patient -- so as you see here, this is a part where the native valve is. And what you see here in the shortcut, that the valve is not really deployed round; it's over -- so it adapts more to the anatomy.

But what does it mean for durability? Also there's a valve that is [a super] on the valve, and the valve itself is located here, also in this part. It's not round deployed. And perhaps when a valve that's not round deployed -- it could have an influence of the durability.

When you see [a city] after implantation of SAPIEN -- so SAPIEN every time, because of the higher radial pulse it makes the annulus round, in most cases. And they are much better deployed. And perhaps this will have an impact of long-term durability. We ask this question a lot because we now treat more and more younger and less sick patients, and we want to have really a long-term durability of the valves.

So this is my last slide. Thank you.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Okay, this is a good point for some Q&A. I think we'll open it up to the audience. Please wait for a microphone, and if you will please introduce yourself.

Amit Bhalla - *Citigroup - Analyst*

Thanks. It's Amit Bhalla from Citi. First question for Larry -- with your lower estimate for new site additions in 2014, you pointed to the NCD. But I'm wondering what aspect does competition have in that estimate? And also for the longer-term opportunity, are there any changes in how you're looking at the addressable market?

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Yes. I don't think competition has any impact on the site rollout. I think it's possible that competitors could add a few sites, maybe, that we aren't in. But generally speaking, I think the sites are who they are and the sites that qualify are the ones that qualify. I think the -- we are going to be a little bit more (multiple speakers) --

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Having said that, Larry, probably our competition will also start some sites next year.

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Yes, they will start some sites next year. Again, I just think the majority will probably be in the same places. We just gave you our numbers for how many sites that we'll start. I think with -- there's two things that could make additional sites come online. One would be just hospital consolidation, I think, which you could see somewhat over time. And the second thing would actually be changes to the national coverage decisions, they could expand that.

We'd certainly hope that with the positive data on the TVT registry, that that could lead to eventual changes to the national coverage decisions. And I think it's been pretty clearly demonstrated this technology can be rolled out and it can be cost-facing.

Rick Wise - *Stifel Nicolaus - Analyst*

Rick Wise, Stifel. Two questions -- one, Mike, could you elaborate your "we will meet force with force" comment? It sounds like, with the new product launches, you're talking about price stability, but I'd be curious to know what you're thinking about.

And then, for Larry, just the seeking to approval by, sounds like, by the end of this month, maybe talk a little -- talk just a little bit about how you plan to roll it out and the logistics, and how quickly and how broadly. Just give us some perspective on that launch in Europe. Thank you.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Thanks, Rick. What I was trying to acknowledge is I know there's some earning estimates that are in place for 2014. And one of our -- one of the alternatives the companies could have sought would be to reduce expenses to try and maximize earnings. We think that would be the wrong move strategically, and we don't think it would create the most robust long-term shareholder value. We're going to continue to spend aggressively. We talked about what we're going to do in terms of upgrading our customers. We're also going to have a robust field organization and fully compete, and then really trying to send a signal in terms of how we intend to compete broadly.

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

So on that, specific to the SAPIEN III launch, again, converting customers from SAPIEN XT to SAPIEN III is a pretty rapid process. It doesn't require a lot of extensive training. There are some different nuances of the device, but they are easily teachable on the bench. So we plan to move really aggressively with SAPIEN III and try to get it in the hands, certainly, of our big customers very, very quickly. A lot of those participated in the European clinical trials, so they're already very experienced.

But we're going to make it very easy for our customers. We're going to exchange out their inventory. We'll offer them an upgrade. Like I said, we're not going for significant price increases. We're going to make it very easy for them. Because we think, when we put SAPIEN III in their hands, it's a very, very differentiated product. And we think it's going to be very popular with clinicians, and it's really going to enhance the patient experience as well.

David Lewis - *Morgan Stanley - Analyst*

David Lewis, Morgan Stanley. Just a quick follow-up, Larry, and then one additional one. In terms of next year, the US market is a little easier to understand because there's one definitive event in terms of share. Europe is a little murkier, but your outlook for next year for share in Europe, for 2014 share in Europe, give us some sense of how you think share will play out in 2014.

And then secondarily, your comments beyond 2014 and 2015 through 2019 path and the market growth you're expecting implies that this device is going to expand into alternate indications, which suggests that PARTNER II data obviously is going to be a key catalyst. Give us a sense, just based on registered data and what gives you the confidence that we are going to see robust outcomes in some of these less-sick patient populations. Thank you.

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Sure. So I think it's hard to get into share conversations. What we try to do is we really try to give you all the things that are factored into our model, and we try to give you the global range. So we see the global range about [$700 million to $820 million]. And we've said [$40 million to $50 million] of that is going to be our Japan sales. So we try to give you guys a tighter range there.

It's a little difficult to predict precisely what's going to happen with all these launches. In terms of the US and expanding indications, we have been very, very impressed with how well the clinical trials have gone. You look at the data that came from PARTNER I, you look at the data that came from the first randomized trial versus surgery, and transcatheter valves compared very favorably, even in the best surgical centers. And that was with centers having all of their learning curve just really starting out almost from scratch.

And so we're very -- you've got to wait for the results of the data, but we're very confident that, even in an intermediate risk patient population, that transcatheter valves is going to show benefits. You've got to run the trial, you've got to meet your endpoints. But we remain confident that's going to be a successful trial and that's going to expand indications for patients.

David Roman - *Goldman Sachs - Analyst*

David Roman from Goldman Sachs. Actually, a question for Dr. Kasel. You talked a lot about core valves versus safety in your practice. Clearly, in the discussion, Larry referenced in increasing competitive landscape in Europe. Can you maybe just talk about any of your experience or will there be other product coming to market, whether it's in the larger players such as Boston Scientific, Lotus valve, St. Jude, Portico valve? And then in Germany, specifically, there seems to be a number of smaller companies cropping up as well. So maybe just if you could provide a little bit of broader context relative to what you discussed in your presentation, that would be helpful.

Markus Kasel - *Edwards Lifesciences Corporation - Proctor*

So, in the German Heart Center, we tried -- not only me, so there are two teams. And most of these devices were not transfemoral; they are transapical devices. So our surgeons, they have more experience with the new devices then me. But I joined a lot of time to a new life cycle. We started -- we did implants, for example, with JenaValve. JenaValve is really an anatomical replacement, a self-expanding valve. But this valve has -- like others, we have to try these valves. They have their pros and cons also. And otherwise we have tried these other valves, and so our experience is that these other valves has a higher pacemaker rate.

We -- so -- but we did only some valve implants that's the Boston device, the Lotus valve. We implanted the Portico from St. Jude's. It has a very similar shape to the CoreValve and also its implantation is very similar, in my opinion. The only difference is that this is an internal system, not as a partner system. So otherwise, Direct Flow -- it's on the market. I never have tried it. Perhaps it's, for very old and frail patients, a good device; but, in my opinion, not for younger patients. Yes. I think that's it.

Glenn Navarro - *RBC Capital Markets - Analyst*

Glenn Navarro with RBC. Two questions -- one, on SAPIEN XT approval in the US, you are talking about a little bit later than CoreValve. And I would have expected an approval sooner, simply because you filed it in April. I don't think there's going to be a panel. The FDA knows SAPIEN well. So why do you think the FDA is taking their time on this valve? Could it be the lead data that came out in the clinical data?

And then the second question is, when Medtronic launches in the US, about 20%, 25% of cases will require a pacemaker. How is that going to get paid for? Is that going to fall under the valve DRG? Or are they going to be able to pay it or get it reimbursed under a pacemaker DRG?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Yes. Maybe I could speak to timing, and Larry, you can talk about the pacemaker and the DRG issues. You know, our assumption about timing -- and again, who knows when it comes to regulatory timing? So this is a very wide range of possibilities. We're just telling you basically what we have modeled. We are assuming that when Medtronic said that they would have approval for the end of their fiscal year, that's April, they must have been exercising -- they must have had a high level of confidence. And a high level of confidence would indicate to us that they'd come even earlier than that, maybe substantially earlier.

So that's really what's in our model. We don't know when we're going to get approval. There's no problem with the SAPIEN XT. We think that's all going very well. What we have said is it's going to be in the comparable timeframe, within a few months. We're not necessarily saying it's going to be a couple of months after it. Really, what we know less about is what the competition is going to do. And again, we hesitate to overpromise in terms of what SAPIEN XT will do, if that provides some insight.

Larry, you can --?

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Yes. On the permanent pacemaker, if a patient gets a transcatheter heart valve procedure and then they need a pacemaker during a hospitalization or, I think, within the first 30 days, that has to be paid for out of the surgical DRG. So you don't get a separate reimbursement for putting in that pacemaker; it's all covered under that one DRG.

Glenn Navarro - *RBC Capital Markets - Analyst*

As you talk to hospitals getting ready to implant CoreValve, how much of that is going to be a limiting factor to CoreValve's adoption?

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Yes, I think that's a good question. We're going to have a panel after, with -- after this with some leading physicians up here, some of which have had experience with CoreValve. So maybe that's a better question posed to them.

Mike Weinstein - *JPMorgan - Analyst*

Mike Weinstein, JPMorgan. Larry, could you -- just two questions for you. First, can you just talk about the design changes on CENTERA, just kind of what occurred over the last year? Obviously, the timeline got pushed out and we knew you were doing some work on it. So you still think -- what did you learn in the process? And what did you change to the product? And I have one follow-up. Thanks.

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Okay. Yes. We're really excited about CENTERA, but it's a different development process than like our SAPIEN platform. So, when we went from SAPIEN to SAPIEN XT, we were able to take everything we knew off of our SAPIEN platform and just transfer it to XT, and the valve performed very similarly. That's very similar to what happened with our SAPIEN III platform as well, as we were building on all of this knowledge and all of this experience. So those programs could go pretty fast.

With CENTERA, it's a very unique product in that it's a short self-expanding frame. And so it has a motorized delivery system. It has GLX issue on it. There's just a lot of things on that platform that have never been done before. So we wouldn't move that program at the same pace that we would move like our SAPIEN platform, because we're really starting from scratch on our knowledge base and our learning experience.

So a lot of the changes we made were really enhancements to the delivery system to improve ease of use. And that's the commercial system that we will be studying early next year, and that's the system that we will bring to the market. So the valve performance has always been very good. We have always been very pleased with the valve performance. It's just mainly the things around the delivery system that we wanted to make sure were great. And for us, when we launch our first self-expanding valve, we want it to be pretty spectacular. We don't want to launch out something that doesn't perform at the highest levels that I think our customers have come to expect from us.

Mike Weinstein - *JPMorgan - Analyst*

Understood. Let me ask you just -- and I saw Mike was here, so maybe he'll comment on this later. But in the TVT registry, which -- the full write-up that was in JAMA -- one of the things that stuck with us was just, from the early experience from that registry, that only 20% of the patients were characterized as inoperable. So we went back, I think, two years ago in terms of how kind of we thought this launch would play out and how this market would develop. I think part of the hope was that more patients that were deemed inoperable that weren't getting treated would start to funnel into the system to get treated.

So, given what we are learning from the registry in terms of what's going on out there, in terms of the real patients, that so far, at least, most of the patients are surgical valve candidates; they're not the no-option patients. How do you -- what are you doing to really stimulate those patients? You guys have talked about being out there but haven't really flown through into the system so far.

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Yes. It's a good question. I think there's a -- you know, I think we're learning a lot. I think one of the things that we knew or we believed very strongly was there's a lot of patients sitting on the sidelines. Now, whether those patients were technically inoperable or whether they were just high risk and didn't get surgery, I think the TVT is really the first good data set that we've had that really helps characterize that.

But even if you go back and look at David Mack's work, he doesn't say that those patients sitting on the sideline that aren't getting treated are all inoperable. He's saying they just have high risk, and they're elderly, they're frail, and they just choose not to have surgery, even though the surgeon probably would be willing to operate on them if that's what they wanted.

So I don't think it's so much about who's inoperable and who's high risk. It's that there's a large number of patients that, when surgery is the only option, just given their situations, they won't pursue it. And we still believe there's a very large population of patients sitting on the sidelines, that we can bring those patients forward. And transcatheter valves is a very attractive option for those. And that's how -- that's why we project the market growing the way it does. I don't think it's really this issue of being technically inoperable. I think it's patients who just won't have surgery, for whatever reason.

Larry Biegelsen - *Wells Fargo Securities - Analyst*

Larry Biegelsen, Wells Fargo. A couple for Larry. Japan, the 20-millimeter approval timing, could you tell us what that is, please?

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

I think we showed it on our chart, but I think it comes in, in the 2015 timeframe, I believe.

Larry Biegelsen - *Wells Fargo Securities - Analyst*

And then the US BTC program, can you just talk about what you've seen so far and your -- the likelihood you'll expand that?

And just one last one -- if II-A is positive, Larry, do you think you're going to need another trial to access the remaining, let's say, 50% or so of surgical valve patients? Or do you think you'll get everything if PARTNER II-A is positive?

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

It's a good question, Larry. PARTNER II-A is going to -- we're going to learn a lot from it. We're going to see, in patients who have an STS score of 4 and above, how this therapy performs. And that's going to be a pretty intermediate risk group. I will say randomized trials -- we randomized 2000 patients in the PARTNER II-A trial. It's a lot of work. Randomization is tough for patients. But what FDA is going to do is make this something that can be available to all patients, I'd hope that we could come up with more creative solutions in another giant randomized trial. But frankly, that's a discussion probably for a later time.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Yes. And on the direct-to-patient piece, Larry, we're still early. We're still running in several markets and really trying to learn. It's too soon for us to draw conclusions.

We have time for one more question.

Bruce Nudell - *Credit Suisse - Analyst*

Bruce Nudell from Credit Suisse. Two questions. First one is -- TVT registry clearly showed comparable mortality, comparable age, but the SCS score was low. Any kind of CMS feedback as to whether there's dangerous creep? -- is the first question.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Yes. Dr. Mack will be on the panel shortly, so maybe this is one that he can expand on. And I'll maybe just give you a little bit of the short answer.

I think it's important to remember that in the clinical trial, the only way the patients could enter the trial was by having their STS score be at a certain value. The risk calculators -- I don't know how many of you have been online, but it's fairly robust. And by robust, I mean complicated and there's a lot of fields. And so, because that was the criteria into the trials, they had to push patients where they put in all the comorbidities until they could take an STS score that they qualified the patient.

That's not the criteria to get treated commercially. The STS score is really irrelevant. The criteria to be treated commercially is that two surgeons review that patient and they view that patient as being suitably high-risk or inoperable to receive the therapy. So, I just don't know that much rigor is put into the STS scoring process in the commercial setting as what was done in the clinical trial.

But we look at the ages, and the ages are the same or actually slightly higher. So I don't think there's good evidence there. But that would be a great question for Dr. Mack to answer.

Bruce Nudell - *Credit Suisse - Analyst*

And my second question is, as you pointed out that the centers of excellence are really driving down length of stay, what -- just for clarity, because I know there's a lot of confusion -- what are the rules? Let's say you're in DRG 220, where average length of stay surgically is seven days or thereabouts, how low could you go? And what percent of patients are going to be discharged to home and still meet full payment criteria?

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

Yes. It's a good question. I think -- as I'm not -- we're going to have our panel of doctors up here real quick, and they're probably going to be able to answer that a lot more robust than I can. I think, at a high level, we didn't focus at all on length of stay early on, and when you saw those seven and eight-day numbers. We've seen what John Webb's group does, where they're getting patients out, really, in a day. I think those are sort of your guardrails.

Can everybody get there? I don't know. But two or three days, four days, especially when you move to lower-profile devices -- I think those are very achievable. But you can let the clinicians, and I'm sure they'll have opinions and weigh in.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Okay. Thanks very much. At this point, we're going to break. Thank you very much, Dr. Kasel, Larry. And we're going to bring the doctor panel up? Yes. Thanks.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

I think now I'd like to turn it over to questions from the audience, and so we'll get the microphones up from the back, and I'll let David pick.

David Roman - *Goldman Sachs - Analyst*

Thank you. David Roman from Goldman Sachs. There was a question earlier about direct-to-patient or a referral pattern. Can you guys maybe just talk a little about where most of the patients you're seeing come from, as it's, more particularly now, about two years post the initial launch in the inoperable patient population? Are these patients that you're seeing otherwise and turning away? Are these patients who are coming from general cardiology referral practices? Maybe just walk us through how you're getting these patients, and if that patient profile has changed over the past, call it 12 months or so.

Unidentified Company Representative

Well, knowing that there are more and more centers, and I think a bit more regional answer to that question. But I can tell you about the New York point of view. We're still gaining quite a bit from, of course, New York and New Jersey; some from Connecticut at our center. And they're basically -- the main source is the cardiologist. Knowing the data are out there the patients are asking for, and then those cardiologists are referring those patients to dedicated centers.

Unidentified Company Representative

So New York's a pretty sophisticated market with pattern. Maybe we could head down to Texas or Louisiana and tell how that works down there.

Unidentified Company Representative

Not sure -- did you just diss Texas?

Unidentified Company Representative

I would never diss Texas. There's too many reasons not to.

Unidentified Company Representative

Well, I would say the referral patterns have changed somewhat over the last couple of years. Early on, we saw a large number of patients coming referred by surgeons, because they didn't want to re-operate on them. We are not seeing as many come from surgeons now, because I think as the commercial rollout happened, those are staying in the commercial sites and not being sent into the referral centers. We are seeing patients -- we are probably turning down more patients than we used to, because what we're seeing is the very high-risk patients that the referral centers don't want to do, and those come mainly from general cardiologists or from heart teams that have turned them down together.

Third is: a lot of the market in New York, their children live in Texas; and their children are very savvy in terms of finding options for their patients to be treated. So a lot of times there's unawareness of a primary care physician about alternative treatments for aortic stenosis, but the children have found it on the Internet. So I would say about a quarter of our referrals right now are direct patient referrals from either the patient themselves, or more often, their children or grandchildren that have been aware of this alternative from Internet access.

Unidentified Company Representative

We get almost all of our referrals from cardiologists. The exception are the children or grandchildren of physicians -- or physician grandchildren who refer their grandparents. Very few regular patients, or regular people, are savvy enough in our area to refer for TAVR.

And we do get some from other TAVR centers who don't have -- they have a limit to how many CoreValves they can put in because of the CMS limit on the post-market approval. And patients who have iliacs that are too small for the regular SAPIEN valve, and they're too frail for transapical, who may benefit from a XT, an S3, or a large-outlet 29 valve. So specifically from other TAVR centers.

Bob Hopkins - *BofA Merrill Lynch - Analyst*

Thanks. Bob Hopkins from Bank of America. So two things, one on the NCD. Absent a new randomized, controlled trial and new indications, is there any reason for us to expect any change in the NCD as we look forward here? That's number one.

And then number two is a question around pricing and profitability. And when you talk about the ability to capture the ancillary testing and the ability to go to mat versus general anesthesia, what percentage of the centers around the country do you think really have the capability to do those two things and therefore get length of stay down? And then just your general thoughts on pricing in this product going forward.

Unidentified Company Representative

I'll answer real quick on the national coverage decision, and then I will let Mack weigh in. I think the national coverage decision will change over time. I think people reevaluate it as the indications expand with the label. Some of the things that are done in the NCD now probably won't make sense moving forward, but I don't anticipate we'll see any changes in the NCD in 2014. And so no change in the NCD is modeled in our plans. Mack?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

I think when we initially filed a request for an NCD, the discussion at that time was it would be reevaluated at some point in time and reopened in the time frame that I remember was three years, or something like that. And I've not heard anything in recent time. You know, the VAD NCD was just revised. But I've heard nothing from CMS that there's any impetus to reopen or revise the NCD anytime soon.

Regarding how many centers will be able to move to local anesthesia with sedation and early length of stay, I think this is work in progress that we're just beginning to scratch the surface on. And I think, kind of like if the TAVR rolled out commercially, it will be a staged rollout, where centers put their toe in the water carefully to begin with. And as the infrastructure builds up and the ability and confidence to do this, you'll see it more and more.

Kind of related to that -- and I think Bruce asked the question earlier about is their disincentive to do this. And I think that there is a fixed DRG payment, and there's a target date for discharge. And it's for surgical aortic valves, and it's usually 7 to 8 days, somewhere in there. There's no penalty for early discharge; however, the penalty comes -- number one, is if the patient is readmitted, because that's still under the original DRG. Or number two, if inpatient resources are used to facilitate that early discharge.

So if you discharge the patient before this target 7 to 8 days to another inpatient rehabilitation facility, there's a penalty for that. Or if you discharge them to home -- and I think in the TBT registry, 65% of patients were discharged to home. Well, if you discharge them to home and you use home healthcare services within the first 48 hours, that's a penalty also. So I think that you'll find that centers are very selectively pre-habbing which patients -- as Steve said, which patients we think have a high likelihood of being able to go home without home healthcare services. And that is the family infrastructure that's around them, what their living circumstances are, and what their frailty status is.

Brooks West - *Piper Jaffray & Co. - Analyst*

Thanks, Larry. Brooks West with Piper Jaffray. Question for the panel: recent data from Medtronic at TCT seems to point to an ongoing paravalvular leak benefit from a self-expanding valve. I'm wondering if you've seen that in your own experience, or if you believe that? And then relating it to the earlier pacer discussion, I'm wondering what the potential benefit from paravalvular leak stroke reduction might be against putting a pacemaker in?

Unidentified Company Representative

Well, there isn't a lot of data, but there is some intuitive understanding of what has happened over the last two years. Initially, and for PARTNER I, PARTNER II, the sizing -- and actually, it continues for PARTNER S3 -- the sizing of the valve was determined by the transthoracic echo diameter. We've learned from our colleagues in Europe and from the Medtronic investigations that the valve and the outflow tract are not around; they're oval. And we were underestimating the size of the valve required for these patients.

So sometime during the end of PARTNER II, and for PARTNER III going forward, we switched from echo sizing to determine the size of the valve to CTA sizing, and we're using larger valves. And so they are being sized more appropriately. So I think going forward, you're going to see that the SAPIEN paravalvular leak rate is going to go down.

If we oversized too much -- as is insinuated by the Lotus Valve trial, where 10% oversizing or greater lead to a higher pacemaker rate -- we may also see the pacemaker rate go up in the Edwards valves as we increase the size. So I think the initial benefit of paravalvular leak, of the CoreValve versus Edwards valve, is going to diminish going forward, as we have more Edwards valves and we size more properly. I think the distance between the pacemaker rates is going to shrink, as well.

In fact, Dr. Sharma, you have experience with ball put. What's been your experience?

Samin K. Sharma - *Mount Sinai Medical Center - Director of Clinical Cardiology and President of the Mount Sinai Heart Network*

Clearly one which we actually, at the timed physical, never understood. That's why you want a trace of 1 plus paravalvular leak in there for SAPIEN correlated with mortality. But there consistently had been shown there is a lot of hypothesis for it.

And actually why doing the CoreValve -- being one of the lead investigator, we were finding 1 plus paravalvular leak at the end of the procedure not uncommon. And I think this can correlate with mortality. It turns out to be the same. In the data presented by Jeffrey Popma in TCT last month, that mild degree in a CoreValve did not correlate to paravalvular leak as a mortality.

What I think the issue now of understanding the CT scan. The CAT scan really sizing appropriately has done a lot in terms of our decreasing the paravalvular leak and understanding that -- I'm sure in the earlier PARTNER trial, given they were leaving mild. But now we know that once we are using our SAPIEN valve, we [almost] patient outcomes at, by and large, with none to place paravalvular leak. And that's why we sometimes dilate to the additional -- inflating by 1 cc and so.

But clearly, the appropriate sizing has become very important. To diminish one is a paravalvular leak; and secondly, once you decrease incidence, they, in fact, will be less.

Unidentified Company Representative

You know, I would second what's been said. The use of CT sizing and the slightly overinflating or underinflating the balloon -- which the Company does not recommend, but sites do anyway -- has fine-tuned this ability to address paravalvular leak. I think this is a long way toward being solved as a significant issue.

The other thing I'd add is with our early but significant experience in S3 right now, we see virtually no paravalvular leaks. I mean, that's virtually gone.

Rick Wise - *Stifel Nicolaus - Analyst*

Rick Wise, Stifel. I was wondering if I could ask the panel a little bit about weak positionability, and how critical it is as this next wave of technology comes. Specifically, when I was at TCT -- I'm saying this as a non-physician -- I found a number of the live SAPIEN 3 cases in Europe. And it seemed that the ability to control the positioning right up front, quickly, easily, might be a benefit offsetting whatever benefits of repositioning -- if you can get it right the first time, one physician said to me, they'd rather not go through the issue of repositioning. So sorry for the long question. But is having a repositionable valve critical to each of you? And how are you thinking about that versus, say, in 3? Thank you.

Unidentified Company Representative

I would say obviously you'd want the greatest flexibility possible. However, I would say that repositionability is much less of a desired feature than we thought even two, three, four years ago. I think the ability to use controlled inflation right now -- you know, the number of valves that I would want to have the ability to reposition is few and far between nowadays. Steve?

Unidentified Company Representative

I agree. The success rate for implantation is extremely high. I mean, it's like 98% or 99%. So it's only that 2% of the valves that we would want to reposition.

Samin K. Sharma - *Mount Sinai Medical Center - Director of Clinical Cardiology and President of the Mount Sinai Heart Network*

Yes. I mean, clearly, that in the past we kind of took it very lightly. That's not right position, you put a second valve. But we learned that -- and associated with additional resources more so than some data with a CVA, valve and valve -- and with anywhere from 5% to 7% had been shown by various studies.

But really, putting this one in goes down to your technical skills. To me one of the success of an interventionary sort of -- the [cellion deploying the tower team,] I would say. Besides, we see the main event in terms of the CV rate, the vascular complication rate. What it is that makes them solve [round and round]? I can tell you, at Sinai now, it's less than 1% for the SAPIEN and 2.2% for Core. But clearly, that number, if you take last one, 100% even for CoreValve, has decreased. But the key is that we consider that very seriously and take all the steps now to avoid the possible -- to just put it in terms -- deploy the valve correctly at the first time.

Joanne Wuensch - *BMO Capital Markets - Analyst*

I'm Joanne Wuensch from BMO Capital Markets. I have two questions. The pre-hab way of lowering costs, so getting a healthier patient coming in -- who is paying for that? And how do you identify which is the right patient?

And then my second question is: if you have a patient come in the door when CoreValve is approved, is there a particular population that is good for a SAPIEN and/or a CoreValve? How do you think about moving one into one bucket or the other? Thank you.

Unidentified Company Representative

I would say, to answer the first question, it's a hard team decision together from a collective experience that determines what those candidates are. And I think the younger, the healthier the patient, the more likely they are to be able to early discharge and go home.

Second, we do not have CoreValve right now. But we do send patients to other centers for CoreValve, and those are ones that either need a larger or a smaller valve; or we do not feel are candidates for alternative access and need a smaller delivery system than what we have commercially right now. So those would be who, I would think off the top of my head, we would use CoreValve for.

Samin K. Sharma - *Mount Sinai Medical Center - Director of Clinical Cardiology and President of the Mount Sinai Heart Network*

But I think also it's the same -- will become center-specific. There will be some centers which will use once -- and we're talking about if, as had been projected, that the SAPIEN XT and Core will be available around the same time period.

So if there is a big lag, there's no question about the CoreValve, because of 18 French. Once become commercially available, lots of centers will use it and will favor it. But once both are available, then it will just become, besides some minor differences -- particularly the issue, which is an important one, actually, of the pacemaker. But it will become more of a center -- in my opinion, center-specific, that some centers will be using one valve more versus another.

Unidentified Company Representative

In the question about who pays for pre-hab -- you pay for pre-hab, just like you pay for everything else. But the idea is that Medicare pays for it, or whoever the insurance is. We send them to a physical-therapy-type setting, whether it's inpatient or outpatient, so they can get more fit so they will survive the procedure.

We don't like to take people who have been in the hospital -- 80-year-olds, 90-year-olds, who have been in the hospital for two or three weeks and try to put a TAVR in them. We try to get them as fit as possible. We do PTI on them; we do balloon valvuloplasty if they have severe AS and heart failure. Then we send them to the rehab facility.

Unidentified Company Representative

Time for maybe one more question, David? We have more time? Okay. We have time for more questions.

Amit Bhalla - *Citigroup - Analyst*

Thanks. Amit Bhalla from Citi. In the context of economics, can you talk about the impact of TAVI on your respective institutional surgical valve programs; and if that factors into the institution's calculations of TAVI profitability, either directly or indirectly?

Samin K. Sharma - *Mount Sinai Medical Center - Director of Clinical Cardiology and President of the Mount Sinai Heart Network*

I think I can tell you about Sinai -- that since it was said that by having a TAVR program, your surgical aortic valve number will go up; or once you're very aggressive to our program, the surgical aortic valve number will go down. At Sinai in the last three years since we have been -- both initially with the CoreValve only; and last year, since May, adding the SAPIEN in our maintaining them, our aortic -- overall surgical aortic valve, or sAVR, volume has not changed.

Unidentified Company Representative

So I think you do have to look at it as a programmatic approach. And yes, there has been a coattail effect of TAVR to surgical aortic valve replacement that we've seen over the last three years. And surgical aortic valve replacement has a significant positive margin for hospitals.

However, over the last year now, we have not seen that growth in surgical aortic valve replacement. That's pretty much plateaued. So although there's been a benefit over the last three years, that's attenuated a little bit right now from a surgical standpoint.

Unidentified Company Representative

And we saw exactly the same trend. We increased about 15% to 20% per year the first three years, and it's flattened out. What I will say is that the surgical patients that are getting operated on are healthier. They don't have to operate on the sick ones anymore like they used to. And so I think the surgical outcomes are going to be better.

Unidentified Company Representative

What do you think about that, Dr. Mack?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

Oh, it's absolutely true. And in the same issue of JAMA that the TAVR -- the TBT registry article was in, there was trends in treatment of aortic valve replacement in the United States from the Medicare database. And it shows that the mortality has steadily dropped over the last 10 years of surgical aortic valve replacement.

I think the way you have to think of this is: this is transcatheter therapy for valves. And it's being introduced exactly the opposite as transcatheter therapy for coronary disease was introduced. So for coronary disease, the patients that were treated with PCI were the lower-risk patients leading the more complicated, higher-risk patients for surgery.

This is exactly the opposite, in which the higher-risk patients are being treated with TAVR, leaving the better-risk patients for surgery. So we should continue to see mortality of surgical aortic valve replacement continue on the downward trend over the next couple of years. And I think that the

clinician decision-making balance is finding where that is -- where you can optimize your center outcome for all patients, by deciding where that line is between TAVR and surgical aortic valve replacement, and the balance between early outcomes and long-term outcomes.

Unidentified Company Representative

Yes, I'd like to credit Michael Mack and Larry, both, with creating this heart team concept. Because this could have been a very divisive technology. It could have been like carotid stenting, where the vascular surgeons and the cardiologists were at loggerheads and at war. This heart team concept is critical -- not only in pushing the technology for it, but in taking care of each individual patient.

Raj Denhoy - *Jefferies - Analyst*

Thank you. Raj Denhoy from Jefferies. A couple of questions, if I could. First, on this idea of expansion indication, referring to Dr. Mack: with the difficulty in enrolling trials as we start to go to less-sick patients, what do you think it's going to take to expand into additional populations beyond the cohort in PARTNER II? Do you think it's just going to stick with the TBT registry, or are we going to need more studies? And I do have one follow-up, too.

Unidentified Company Representative

So that's a $64 question that I have no idea what the answer to is. By the time we get the results of PARTNER IIA, which is a -- and SURTAVI, which are two-year endpoints. So this is -- what, early 2016 that we potentially could have an indication for intermediate-risk patients.

For me to know what's going to happen after that -- it's way above my pay grade of figuring that out. I think that part of the idea of the TBT registry and the NCD mandate for it was coverage with evidence development. I think we've seen some of the benefit of that already, with the FDA expanding the label to alternative access patients from looking at what's in the TBT registry. So I would think that somehow, some way, that's going to play a role. But I haven't got a crystal ball as to how the regulators are going to figure that out.

Unidentified Company Representative

It's a very hard population to define, too. I mean, we can define operable and interoperable, and we can define low risk; but the intermediate risk is sort of a nebulous target.

Raj Denhoy - *Jefferies - Analyst*

And my follow-up is: we're entering a period now where you're going to have -- to your earlier point, as well -- the TAVR valves are going to be approved for the more sick patients. How are you, practically, going to manage that? Will you still take your moderate-risk, high-risk patients and subject them to SAPIEN? Or will you use SAPIEN XT when it gets approved?

And when SAPIEN 3 gets to the market, are you then only going to relegate that to the high-risk patients? Or will you start to expand it into the patients for which it's not going to be indicated initially? And will reimbursement, perhaps, be the hurdle that keeps you from doing that?

Unidentified Company Representative

I think that centers are, for the most part, paying very close attention to what the labeling is and are very reluctant to go too far off-label in terms of use. So I would think that, as we know it right now, that the potential for approval in intermediate-risk patients is SAPIEN XT. And then whenever SAPIEN 3 gets done and gets approved, that's going to be for inoperable patients.

So it is a little bit of a dichotomy there. You're going to have the latest-generation valve only being able to be used in the higher-risk part of the population. But I think it's way too premature to speculate how all that's going to turn out.

Raj Denhoy - *Jefferies - Analyst*

Just one quick clarification. The S3 trial that they're running now is high-risk and inoperable, so it would have that indication. It wouldn't just be inoperable?

Unidentified Company Representative

Yes, but I met intermediate risk.

Raj Denhoy - *Jefferies - Analyst*

Correct. Correct. And I think the way that the NCD is written, where everything is tied to the FDA label indication -- I think centers are very sensitive to that, and probably for good reason.

Kristen Stewart - *Deutsche Bank - Analyst*

I am Kristen Stewart from Deutsche Bank. Just as a follow-up for that, SAPIEN XT -- Larry, can you just remind us: are you only going for the label indication of inoperable-only? And then for the panelists, I guess, following there, how will you treat or how does your hospital view reimbursement? If SAPIEN XT is in fact only labeled for inoperable? Will you then have to continue to use SAPIEN in high risk?

Larry Wood - *Edwards Lifesciences Corporation - VP of Transcatheter Heart Valves*

So to answer your first question, the study that was done for SAPIEN XT for PARTNER IIB was evaluated in inoperable patients versus SAPIEN. But we do have randomized data looking at SAPIEN XT versus SAPIEN. So we'll certainly have that discussion with FDA.

We don't know what label they'll ultimately give us. Obviously, it gets complicated for physicians if XT has an inoperable label and SAPIEN has a high-risk indication. We think there is a lot of evidence there that would support having the full indication, and that's certainly what we asked for. But it's impossible to predict what FDA will eventually do.

Kristen Stewart - *Deutsche Bank - Analyst*

And then, I guess, maybe another question for the panelists. As you are looking ahead to all the other valves that are going to be going into clinical trial, can you maybe just give us your thoughts on how maybe SAPIEN may compare; or your level of interest with valves such as Portico, Lotus, and then Direct Flow as well?

Unidentified Company Representative

Well, I think the SAPIEN valve, again, is a good valve. The delivery system is a first-generation delivery system. I think these other valves have better delivery systems. I think the SAPIEN XT and the S3 are going to compare very favorably with all the other valves that are approved in Europe and undergoing trials here.

Samin K. Sharma - *Mount Sinai Medical Center - Director of Clinical Cardiology and President of the Mount Sinai Heart Network*

I mean, it will be the same way like we had when we got second-generation stents when we compare it with the first-generation. All second-generation stents are better than first-generation. So same thing will happen as a part of the technology evolution, that the newer-generation valves which will come, whether from Edwards or from others; they will be better than the existing one.

And so the time, then, will come is that what is approved? And the language wise, and knowing that everybody's paying a lot of attention to the TBT registry, and make -- from the CMS point of view, you need to fulfill all the requirements for the hospital to get paid.

That's why this whole market, of the high risk and the action risk aortic valve, has been controlled. And basically, that you can use it only in those approved cases and approved indications, basically. And you fulfill all the -- he already mentioned the special requirements. But clearly, no matter when and what, once you have a newer-generation valve by any device company, it will be better than the earlier generation. That is what we need: to live and learn and use the best what is available.

Unidentified Company Representative

One more question?

Larry Biegelsen - *Wells Fargo Securities - Analyst*

Thanks. Larry Biegelsen, Wells Fargo. Edwards has about 280-some-odd sites in the US right now; Medtronic, 40 to 50. Can you talk about the importance of first-mover advantage? And assuming that SAPIEN XT is approved roughly the same time as CoreValve in the US, would you see the US market playing out roughly 50%/50% market share? Or do you think -- how significant do you think the first-mover advantage is for Edwards and SAPIEN in the US? Thanks.

Unidentified Company Representative

I think doctors are going to use the valve they think is best. I don't think the one they get first is necessarily -- it has a little advantage, but it doesn't have a tremendous advantage. And the main limitation in the US of doing transfemoral TAVI is the size of the delivery system. That is by far the main limitation. So as the delivery systems all become around 16 to 18 French, I think that that will not be a differentiating point.

Samin K. Sharma - *Mount Sinai Medical Center - Director of Clinical Cardiology and President of the Mount Sinai Heart Network*

And actually, you know, we talked about the conscious sedation without anesthesia. It's still very small -- small percentage of centers are using that, I think largely because of the cloud. Just to give an example, in 42 sites in the CoreValve -- only 8 centers use conscious sedation routinely. And we are one of them, but still, going to the intubation just to have a better control --.

When I think of the experience and being a comfort level, and particularly, once you have done these cases under conscious sedation, how quick the recovery; how early the discharge of those patients. So instead of your routine five days, you can send the patient home after 48 hours; and as long as there is no penalty of early discharge, it will continue to make people comfortable. And we'll use the valve that they're most comfortable with.

Unidentified Company Representative

I think there is something to your point. I see very few centers being added that aren't already doing one or the other. And clinicians fall back to where their comfort level is. And the majority of sites have SAPIEN experience first. So I think that that is the default strategy. Now, there always will be testing the waters, and venturing out. And like I say, in our own institution we have patients that we can't treat right now. But there is

something to be said about the first device that you had experience with, having your comfort level the greatest; and I think that will be a factor going forward.

Unidentified Participant

All right, I'd like to thank our panel. Thank you very much, guys. We really appreciate your time here and your answering our questions. Thank you.

We will take a 15 minute break at this time. 15 minute break.

Don Bobo - *Edwards Lifesciences Corporation - Corporate VP, Heart Valve Therapy*

My name is Don Bobo, and it is my privilege to talk a little bit about the Surgical Valve business. And we actually have, I think, an interesting combination we're going to give you a chance to experience.

I'll talk a little bit about the Surgical Valve business. How we look at the market, our investments, and what makes that -- continues to be a very exciting business for us. And then we're going to transition to a panel, and we're going to ask several physicians -- Wes Pederson, Mike Mack, and Randy Martin -- to come up and talk about the [mitro] opportunity. I know many of you are interested in that.

So in the panel, we're actually going to shift and spend most of that 20 minutes on the mitro opportunity, the market, kind of how the physicians see some of the emerging therapies. And then I'll come up after that and we'll do some Q&A on the mitro opportunity to surgical business. So, looking forward to getting into this.

We are very confident in that the outlook for the surgical business is pretty strong. And it's really driven by two things. We believe we have a very stable and growing procedure base. I'm going to talk about this broadly. Remember we've spent most of the morning on aortic stenosis. It is the most frequent valve intervention.

But when I talk about surgical valves, I'm talking about aortics, mitrals, tricuspids; kind of the broad set of therapies. And we really believe this procedural market can sustain the single-digit growth rates for the foreseeable future. And it's driven by several things. It's driven by some patient demographics, and I'll actually get into that a little bit more detail, but it's also driven by some of the investments that we are making to improve these options and therapies for patients.

This leads us to a lot of confidence in our strategy that it will not only treat patients well but give us a chance to extend leadership. And I look forward to walking through a couple of our pipeline investments -- they've made meaningful progress this year -- as well as our continued and increased investment in evidence.

And we think all of this will come together to provide better options for younger patients. And we'll spend a little bit of time today trying to bring that to life.

Let me first look back on 2013. Those of you that remember the beginning of the year know that we got off to a pretty slow start globally in the Surgical Valve business. But this business has come back with a lot of momentum. I believe the second and third quarter, we were above 5%, close to 6%, globally. We like the momentum; we continue to see that.

It was a nice year for us in China, where we actually were able to get all of our pericardial products approved for the first time since 2006. So this is an exciting relaunch for us, and I think we've been very pleased with the reception of these products and the market-leading data.

We continue to invest heavily in evidence. And you guys are very familiar with the evidence investments we make for a lot of the newer platforms, but, increasingly, for innovation to be valued we think we have to come with evidence. And so I'll talk a little bit about today some of the progress there and some of the results that that has driven.

I also want to mention, in 2013 we did receive FDA observations for our Draper facility. We've responded very quickly to those. We believe we responded fully, and we look forward to that matter being behind us with the FDA. And lastly, 2013 we believe was a year where we gained share in all the major regions except Japan, where we had a competitor launch a valve.

One of the questions we get asked frequently is, so Don, do you really think you can grow the surgical business. Don't you know that transcatheter valves are going to cannibalize part of that market? Prices are under pressure, and we do understand that. And as look forward particularly to expanding indications and continued innovation of transcatheter valves, we do expect that it will begin to cannibalize isolated surgical [AVRs] more. And maybe there's a little bit of price pressure globally.

But we also believe strongly that there are four elements that continue to drive positive mid-single revenue growth. Growing elderly population; you all have heard many folks talk about that, so I won't spend more time. But we also believe increasingly younger patients are very interested in tissue solutions. And we think there's some specific innovations that we're developing that will make that appetite for tissue innovation actually a reality by having products that are specifically designed for that group.

We have a number of investments in our pipeline that we think will continue to drive revenue growth as customers adopt higher-value products. And then, of course, emerging markets are increasingly interested in treating valve disease. And so we see nice double-digit procedural growth in a lot of our emerging markets.

The cornerstone of our approach is to make sure we align our investments with what's really going on. We're very pleased with the pipeline, and I'll say it's fairly simple. I go back many years, we would've had more than two or three investments. We've concentrated our investments in innovation that we think can really move the needle for the patient and innovation that we think we can generate evidence for. And I'll be walking you through the ZETA platform, GLX, and the INTUITY system in a few slides.

Increasingly, we are even more committed and passionate about developing evidence. We have 25-year study in the last 10 to 12 months rolled out out of France on a mitral and aortic valve showing an expected durability of 17 to 19 years. We think that's very important as patients and physicians get a chance to make their choice around which valve they use.

Going forward, we also think there's a third place we will be investing. We call this commercial innovation. And this really speaks to -- we believe there's an opportunity to more closely partner with valve centers and physicians to go at the under-treatment of aortic valve. So this year, we're rolling out a branded program we call [Valvenet]. I'm actually not going to spend a lot of time bringing it to life here, but stay tuned; we'll be talking more about it as we go forward.

One of the questions we get asked is, so you innovate and you think you really do something meaningful for patients. Do these platforms get adopted?

And as we look back historically, at the top you see the four major evolutions in surgical innovation, mechanical valves, which simply was addressing a basic need for patients who have no option if you have valve disease. The emergence of porcine valves, which allowed valve disease to be treated without the need for lifetime Coumadin. The emergence of a pericardial valve which addressed the principal complaint in porcine valves, and that was durability. And then each of these products became a significant or the majority of our sales in our business. And as a market leader, we think that's important validation for the way these products impact the patients.

Similarly, going forward, as we invest in INTUITY and ZETA and GLX, we have a lot of confidence that the improvements to minimally invasive surgery and the expanding options for younger patients give us a real chance for these therapies to become the majority players in their segment.

One of the questions we ask ourselves is, so is the innovation largely focused on our advanced valve platforms -- the SAPIEN in all of its forms, INTUITY? Well, actually, we're making a couple of other moves. This year, we will stop making porcine valves. We believe the evidence continues to build that the pericardial platform is superior for patients, gives them a better early and long-term result. And so we believe that the brightest move for our physicians and patients is to focus all of our commercial time on that.

We also think there's a remarkable chance to innovate in the core business. We sell about 180,000 to 210,000 valve units per year; repair or replacement. So there's a huge market that consume our current base product we think would value and benefit tremendously from our ZETA and our GLX platforms. And perhaps this gives us a chance to treat a patient a couple of times in a lifetime; maybe once with a surgical valve when they are younger, maybe a second time with the transcatheter valve. And wouldn't it be great if that was the extent of the intervention for valve disease? So this is a little bit of a vision behind these platforms.

Let me talk about our GLX platform. And this is something we haven't spent a lot of time, but this is very, very exciting to us. It has been in development for 10 years. And it is a tissue processing and tissue treatment technology for bovine pericardium. Now, this originated with scientists who said, look, the principal failure mode long-term for pericardial valves is calcification, and we can fix that. And they began to test and try a number of proprietary approaches to do that.

Curiously, along the way, we ended up with other benefits that we think are very interesting. For example, the valve was not stored in glutaraldehyde; it's actually delivered dry in air. This allows us to pre-mount and prepackage valves on delivery systems; think INTUITY. Larry shared with you our CENTERA platform that actually uses this technology.

So in addition to enhance durability, we think there's some very interesting ease-of-use opportunities here as well as a more efficient system for the hospital. Now, this platform actually has allowed us to consider a couple of new products. The first is a tissue aortic conduit that's preassembled and delivered to the physician. Most physicians that need to do this procedure, it's called a Bentall, they'll use a mechanical valve conduit. And, curiously, a lot of these patients are younger, in their 50s. Some patients assemble this on the table to use a tissue valve. This gives us an opportunity to match our GLX Magna Ease platform with the market-leading VascuTech graft and give patients, we think, a very powerful option. We expect this will be launched in 2015 in Europe and 2016 in the US, and we think this is a nice step forward for younger patients and gives us another source of growth in revenue for the business.

This also gives us a chance to go harder at younger patients. If you are able to generate the data and the evidence to inspire confidence in extended durability, the patients that are interested in tissue solutions, we think this aligns nicely with that.

And then we have gone slow. We have built evidence of animal -- multiple animal models; [sheep] model. We've been in a clinical trial in Europe; we have one going in the US. Again, for us to come to market with this product, coming with evidence, we think, is the most powerful and meaningful way to do that.

GLX also enables this new ZETA platform. Now, this is built on our PERIMOUNT design. One of the gifts we have with the longevity of our data is it's a valve design that we are able to adapt with the new tissue platform but not change the fundamental valve design.

This continues to give confidence to patients and to customers. We think this can accelerate the mechanical to tissue conversion. And we also think this provides a very interesting opportunity to eliminate most of the downsides when you try to do a transcatheter SAPIEN into a biological valve. There are often challenges with visualization. Oftentimes, you lose effective orifice area and hemodynamics. And you see a picture here and an animal with a SAPIEN inside, a ZETA platform, and we were able to give that animal in this case the same hemodynamic outcome as they would've had without the bioprosthetic surgical valve. So we're very excited about this. It's still early, but we think this becomes a very important product to younger patients.

You're familiar with our INTUITY system. We're pleased with the progress. We think there are some very important goals for physicians, for patients, and for hospitals, and I wanted our -- a couple of slides on the evidence.

We did something with this platform we have not really done before in the surgical business. We got CE marked, and we promptly went into multiple trials. We didn't try to commercialize it broadly. And the reason we did this is we felt there was a value proposition around surgical duration, gradients, and patient benefits that would be compelling. In 2013, we were able to treat over 1500 patients with this product, and we're very pleased and have confidence that the anticipated benefits will continue to support this product and evidence will continue to emerge over the next year and a half supporting this value proposition.

In fact, as we began to develop the evidence, part of our dream was using this evidence with our physician colleagues in Germany to try to secure early reimbursement. And I'm very pleased to let you know that Germany did map this category of valves to higher DRG. So this will be paid another roughly $4000 in 2014, which, with the flexibility we provided in pricing, we think in combination this will drive and enable broad adoption in Germany. So we think this is a nice step forward for an evidence strategy, getting physicians to partner, and then getting the respect from the reimbursement agencies for this innovation.

Limited commercialization in 2013. 2014, pending the CE mark which we expect any day now, we'll be launching this in Europe. We're ready for the launch; we have inventory, the team is ready to go, and we're looking forward to that. It also will allow us to launch in other regions that take the CE mark as their regulatory approval.

These are the timelines. This is probably a 2016 launch in the US, given the traditional approach to valve trials. And these are the milestones that we've set for 2014. In addition to the valve milestones, we have a number of exciting, minimally invasive procedural labels that our [CSS] division will be bringing forth as well, and we think these will be highly valued. I also want to let you know we did finish the expansion of our Singapore valve facility, and it's doubled our capacity. You'll recognize the facility on the right; we've had up for several years. The section in red, we just validated and we look forward to the products coming up there.

And the combination of a growing procedural base and our investments, we really think this drives stable predictable growth in this business. And as we've gone through our progress with evidence and the pipeline, our confidence is even higher this is true. We also believe this has a real chance to increase our leadership as patients and physicians consider our newer products, better answers for their patient group.

So in summary, in conclusion, if you look at 2014, we expect to grow 4% to 7%. Again, we're exiting the second half of the year close to 6%. The incremental growth is substantially from additional INTUITY traction in Europe. And these are some of the headwinds and tailwinds; we do expect there to be a number of things going for us and against us, but we think our plan takes all of these into account.

So, let me transition. This is a hard transition because we want to ask the physician panel to come up. So Randy Martin, he is the chief of structural valve center at Piedmont Hospital, a cardiologist, a teacher, and probably one of the most knowledgeable physicians on valves.

Wes Pederson; Minneapolis Heart, Abbott Northwestern, director of their TAVI program. And Wes also is involved in a number of the clinical trials and new platforms that are looking at percutaneous or transcatheter mitral interventions.

And then, of course, Dr. Michael Mack.

We've asked Randy Martin to come up and spend about eight to 10 minutes framing the mitral disease space. Then he'll interact with the panel for about 10 minutes. I'll then come up, and we'll have a final segment of 10 minutes where we'll take Q&A from the audience.

And last thing I'll mention, if you have read ahead in the book, Mike will be talking about our transcatheter mitral program toward the end of this session. I'll ask that most of those questions be saved for after Mike's presentation. But we'd love to get into this space, other therapies, repair versus replacement, etcetera. Randy?

Randy Martin - *Piedmont Hospital - Chief of Valvular & Structural Heart Disease*

Thanks, Don. Good morning everybody. Good to see you. Can you hear me okay? If I stand behind the podium, you won't see me, so I'm going to stand out here. Do you know what paraprosdokians are? The term that says it's a sentence -- it's the second half of the sentence is unexpected and funny, usually. And Winston Churchill's favorite one was light travels faster than sound, that's why a lot of people appear bright until you hear them speak. So I hope that's not me. (laughter)

Here we are looking at the prevalence of disease, valvular disease. And certainly with our aging population -- right now, 14% of America's are over 65; in 2030, when I'll be 87, because I'm almost 71 right now, 20%. So it's an aging population. The comorbid condition and the prevalence of heart and valve disease is going to show dramatic increasing.

And when we think about that -- we talked this morning about aortic valve disease. Certainly very important, something that I've spent a lot of my lifetime dealing with. Mitral valve disease is the most common type of heart valve condition in the US. And this is pretty important for you to recognize that it is about 8% to 10% to 12% of people as you age have significant mitral regurgitation. And make no mistake about it; if you leave mitral regurgitation alone, you have a heightened increase in LV failure, pulmonary hypertension, atrial fibrillation, stroke, and death. And that's a very, very important thing for us to remember.

Now, if you look at the population base of the mitral valve regurgitation, if you drill down, there's probably about at least 2.8 million people who have mitral regurgitation that is at least moderate or more significant. I've spent all of my life in the [Echo] world, was fortunate in my early days at Stanford back in the '60s and '70s to get in on the ground floor of Echo. So I have spent my life as a clinical cardiologist who specialized in running Echo labs. Been fortunate to do it at Stanford, at Mayo, at Virginia, and at Emory for many, many years and now at Piedmont. So I deal with this and see this all the time, so I think it's very important.

We've had some great discussions about aortic valve disease. You all are well familiar with this. The advent of TAVI and TAVRs has been one of the more dramatic events in my lifetime in medicine. I will tell you, I've never been more excited about medicine today. The advances are incredible, but we all, Mike and Wes, know that our prime goal is improve the quality of the individual patient's life. And having participated in the first TAVR that was inserted -- I was doing the Echo and Peter Block was doing the insertion at Emory -- it was more one of the more dramatic things I've seen.

But the difference between as we talk about aortic valve disease and mitral valve disease is staggering. The mitral complex is made up of the mitral annulus; it's made up of an anterior and posterior for the mitral valve. These delicate [cordies], which are incredible structures. The papillary muscles, which sort of line up the valve and keep it in the right position, and the ventricle. So you begin to get a feeling of the complexity of disease processes that can approach this and how you would attack it.

Knowing that you all are incredibly smart, but many of my colleagues in medicine are not this smart, there are really two ways to think about mitral regurgitation or mitral valve disease. Primary valve disease; that means the valve is defective or has disease, it leaks, or becomes narrowed, and that makes the heart sick. Or secondary valve problems, where the heart itself -- a change -- often change in the size of the ventricle or the structure of the ventricle causes the valve to leak. So we talk about primary, organic, or degenerative mitral regurgitation and secondary or functional mitral regurgitation.

Now, these cartoons on the bottom that I've highlighted are from David Adams' work. David has done some of the premier work in mitral valve repair, and is certainly a respected colleague, shows that the degenerative disease, where it's primarily the valve and the support structures, comes in all sorts of different shapes and sizes. It's sort of like me and Don Bobo. I'm five feet five on a good day and Don's a little bit taller, so we are in different sizes. And so the complexity of the disease as it goes along becomes impressive if you're trying to do operative intervention. I think there's no doubt, and Mike would certainly -- is a fantastic mitral repair surgeon, mitral valve repair clearly improves preoperative survival, life expectancy, preserves LV function. But the caveat is that it's got to be done by a skilled surgeon; somebody that does high-volume, has high experience. Because operating on the valve on the right, the Barlow's valve, is a heck of a lot different than operating on what we would say is a simple P2 prolapse in the middle.

So if we think about degenerative mitral regurgitation, repair is excellent if done well; that the average CV surgeon does very few of these, again, will [cost] the complexity of this. And there's no doubt that the knowledge of when to refer patients for operative interventions or considerations is very woefully inadequate among the cardiology colleagues, and so that's been a big problem.

So let's quickly shift to secondary functional mitral regurgitation. So think about this on the right-hand panel up here as the ventricle dilates due to an idiopathic situation or commonly post MI, what's called ischemic mitral regurgitation, where under the little diagram up there, the inferior or the posterior portion of the ventricle has had a heart attack. That scars, the ventricle remodels. And look at these capillary muscles; instead of lining up under the valve, they are displaced, and so it's now almost like the doorjamb is too wide for the door. The door may be okay, but it can't close properly. This a gigantic problem. And if you have -- if you develop mitral regurgitation after your heart attack, your survival is dramatically lessened. So any MR in this situation or with the dilated cardiomyopathy gets to be a real problem.

So functional mitral regurgitation, the second big umbrella in this, medical management is ineffective and improving survival, and currently there's been a tremendous lack of knowledge about not only the best time to intervene but the best way to intervene. Very complex disease. And I would surmise, Mike might disagree with me or Wes might, that the cardiologist has very limited knowledge in this is beginning to come up and degenerative MR.

But there is new information, and the new information is shown here. Call your attention to the upper right; this was an article that was just recently published by Edgar and others in the New England Journal. The assumptions about the relative benefit of repairing the mitral valve -- that was often an angioplasty ring and functional MR being better than replacement -- has been recently challenged in a nice clinically controlled trial. And found that while there was no short-term difference in survival between repair and replacement, that repair tended to cause more MR to come back over time and cause the disease process to progress. So it will be very interesting to see what Mike and Wes think about that.

So as we near the end of this -- when we think about future therapies, this is a gigantic market. I am not kidding you because I deal with it every day as a clinical cardiologists in a busy -- very, very busy practice, is that functional MR, about 16% of people have surgical approaches right now in degenerative MR; 53% at most have approach. And, again, the knowledge of the cardiology community is only coming up. So I think that there is tremendous need and tremendous opportunity for very innovative therapies in this space because, again, going back to the key caveats, are we going to be able to improve that patient's quality of life and quantity of life.

Of the available devices, if we look at mitral valve repair, surgical repair, it involves multiple different techniques. It is the gold standard in degenerative MR, but I think, as Mike would agree, only have done well. I don't want to send my patient or send you all for repair and have you come back in six months or year with recurrent repair. So it has to be done well, and prostatic valves with chordal sparing technique may be very important in functional MR and possibly in some patients with complex degenerative disease like that far right-hand panel that I showed you versus a poor repair. The mitral cliff, as you are well aware, has been recently approved for the prohibitive risk patients with significant symptomatic degenerative MR, and it may change our thinking a little bit.

And ending up with the last slide is that transcatheter repair -- surgical repair, as I've mentioned, uses multiple different techniques, and this is going to be a little bit challenging for the transcatheter approach. Wes, I'm going to be interested in what you have to say, and Mike as well, to try to emulate that. But transcatheter replacement, I have no doubt, is coming fairly rapidly because it may allow us to treat multiple pathologies. It will be important to preserve those little cordies because they do play a part in the structure of this.

I think one thing -- and, again, I heard somebody earlier this morning say that one of the exciting things in my lifetime and especially in my early days at Stanford, I got exposed to outstanding cardiac surgery as the Stanford group was then and still is with Craig Miller and others, is that this concept of a heart valve theme which Mike and David Holmes and others have done for the TAVR. The TAVR has really changed our way of thinking about how we approach patients, and I think this is going to be something very, very forward thinking as we come forward.

If you look at these new guidelines for transcatheter mitral valve therapy, or an editorial that (inaudible) the president of ACC president elect president of the AATS for the SCS and the Society for Cardiovascular Intervention just came out with an article that said basically you need a heart team, you need centers of excellence, you need close cooperation and collaboration between industry and physicians, something that I know in my own field of ultrasound has always been very important. And then we have to have clinical data and registries that drive this forward so we are responsible in delivering this. Mitral regurgitation is a big space; it's going to be increasingly important. I'm asked all the time by my colleagues, what should I do with this patient, where should we do this or that? And so I think that would be it.

And with that, I'll stop. And let me ask Mike and Wes -- so was I off-base or was I right in some of the things? What do you think?

Unidentified Company Representative

No, not at all, Randy. I have a lot of feelings, and there's still at this point time a lot of disagreement between interventionalists, echocardiographers, heart-failure doctors, surgeons, and those groups against each other. And it's getting a lot easier to have the conversations because now we have these multi-specialty groups that we made for TAVR once a week, and it's really going to be extremely helpful to move things along.

I think that the first thing you have to do is -- and you've got the ball rolling -- is realize that this is a very complex valve with multiple different causes, and the mantra has always been there will never be a one-size-fits-all which is different than a passive valve like an aortic valve. And I'm less certain about that than what I used to be. And I can come back to that after Mike maybe weighs in on all this.

But a lot of the things that we have been looking at, particularly in the transcatheter world, are based on some successes that have happened in the surgical world which maybe aren't that successful or uniformly successful. And they are -- they don't deliver as effective as a device. So I think the focus really needs to be on valve replacement for most of the cases. Not all of them still. Mike?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

So, of course, you are off-base Randy, but that's beside the point. (laughter) You did touch on some key parts of this. So first of all, wind the clock back 12 years. I totally mispredicted the way that transcatheter valve therapy would roll out. I thought that mitral would come before aortic because the market was so much larger, the clinical unmet need was so much larger, and the failure mode of the device didn't work was so much less. In other words, you didn't die, you just had continuing mitral regurgitation. But I obviously was wrong on that. The clinical unmet need still is there. I agree with you, it is absolutely huge. But it speaks to the problem -- a couple of problems of why it's taken so long to roll out.

Number one, first of all, the market is FMR and not DMR. DMR is a market, but it's a small market. Mitral (inaudible) approved for high-risk DMR, and that's appropriate because there are a lot of patients in their 80s that have had two previous bypass operations that we don't want to operate on. But the functional MRs are where the huge market is.

Despite the fact that we operate on these patients, it's never been shown that correcting the MR changes the course of the disease, and that's what the COAT trial of the mitral clip is designed to show right now randomization versus medical therapy.

The second is that the NIH trial that you mentioned of severe functional MR repair versus replacement has shown that replacement is more durable than repair, and I think that's going to catalyze this whole field and catalyze it towards replacement rather than repair.

So there are challenges of anchoring the valve. There are challenges of delivering the valve. But I think that functional MR and replacement versus repair is what we're facing in the near future of transcatheter valve therapy for mitral.

Randy Martin - *Piedmont Hospital - Chief of Valvular & Structural Heart Disease*

I think you're right. It's interesting when you think about degenerative MR. If you see a 65-year-old or a 60-year-old or a 55-year-old patient who has degenerative MR, historically the cardiologists have sat on them, waited for them to develop atrial fibrillation, waited for them to develop pulmonary hypertension, none of which is reversible by operative approach. So I think that's going to be important.

Mike and Wes, do you think that there is knowledge among the cardiologists about the difference or the physicians about the difference in the aortic and mitral space, two different diseases? Do you think we're getting more knowledgeable with that?

Randy Martin - *Piedmont Hospital - Chief of Valvular & Structural Heart Disease*

Minimally. And I think there has to be a lot of education that is going to be done. Some of it is going to come out of trials and registries and publications subsequent to that and then, in conjunction with the industry, after the devices come out, rolling this stuff out and putting teaching programs in place.

But I think the difference between degenerative and functional and which ones do better, it is not uncommon for me to see cardiologists today that don't understand that when you repair and do a good repair, which is usually a restrictive ring annuloplasty and a functional MR, that they fail in five years. That is totally different than a degenerative and a favorable degenerative and whose hands it is in and which centers it is in. And so you really get restricted down.

And I think because of those restrictions, depending upon how much and how successful we are going to be at driving patients to centers of excellence, who do great repairs who can repair anterior [leaflets] as well as posterior leaflets if you put something very simple in someone's hand that is reasonably effective and this may be, to a certain extent right or wrong, they are an 80-year-old individual, they have degenerative MR and they have calcification in their annulus, I think that even in the degenerative's valve replacement is going to play a role the more complex it is.

I mean, the majority of my -- of degenerative mitral MR are a posteriorly flip prolapse. The approach to that surgically is straightforward with a good repair surgeon, he is going to get a success rate of greater than 90% -- 95% or 1% mortality. That is a smaller group. It is the functional MR patients that are the real big group that I think we are going after here.

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

Yes, I would agree. And I would say that where are those patients right now, what are they being treated with. They are in heart failure clinics and they are being treated by heart failure specialists and a lot of mid-level providers. And the treatment is medical, plus minus resynchronization therapy on appropriate patients. And heart failure specialists are, for the most part, nonbelievers that intervening on the mitral regurgitation changes the course of the disease. So I think that there's two things that potentially could change this.

One is the co-app trial of MitraClip that is being done. If that shows a benefit of intervention, that will catalyze the whole field.

And the second is that if you have a less invasive therapy then your threshold for treating that patient will go down. So in other words, a lot of these patients with FMR are very sick patients and we are reluctant to operate on those patients because it is a huge operation with maybe some benefit, maybe not.

Well, if the invasiveness of the procedure goes down, your threshold for using that procedure will change.

David Erickson - *Edwards Lifesciences Corporation - VP, IR*

Let me ask you if I can, Don, take a second. You -- because we want to talk a little bit about the potential for transcatheter therapy. Or I do, I want to learn from you. Mike, are you saying that you don't think that there is an opportunity or a big opportunity for degenerative MR in transcatheter techniques? Whether it is [chordal] techniques, whether -- those sort of things, is that the case?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

No. I think that there is definitely a role for it and because we use MitraClip in those patients. There is a group of patients that are high risk with degenerative disease who are candidates for transcatheter therapy. And be that -- and for the most part those are patients that need something done to the leaflets. So either MitraClip or artificial cords. But the bigger opportunity in clinical unmet need is functional MR.

David Erickson - *Edwards Lifesciences Corporation - VP, IR*

Okay. Wes, would you agree with that?

Wes Pedersen - *Minneapolis Heart Institute/Abbott Northwestern Hospital - Interventional Cardiologist*

I would definitely agree. I was going back in an article actually it was on -- it was the EVEREST II trial and you look at the four-year follow-up now and I think we all would have assumed -- and these are patients in their late 60s, I think, for that trial, not 70s and certainly not 80s, and most of them were degenerative. But if you look at the functional group, the failure in the functional group as we were just talking about with other retrospective trials is quite high. And so, 25% of those patients have not died, have not got another procedure and have mild MR still. And with the clip it's in the 30% range.

So even with the only repair device that I think has much validity at all, you have a 34% success rate in these functional MR patients that -- four years out. And I think that is inadequate. I think that we can do better.

David Erickson - *Edwards Lifesciences Corporation - VP, IR*

Make no mistake about it. I think that the mitral space is a big space. I mean we see a tremendous number of patients. I don't think there is any doubt about that and I think as we look forward that, Mike, as you said you predicted it would be first, but I think we have learned a lot from the TAVR approach, not only systematically, but platform-wide.

Just in essence so do you think is there one particular type of disease complex with the mitral that is more -- suits better for, say, a transcatheter replacement or a repair?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

So, again, I think it is functional MR. It is functional MR whose ventricles are not too advanced. And the other thing that I thought all the way from the beginning is that the transapical approach is an ideal approach for the mitral valve. It takes away a lot of the complexities of some of the delivery aspects of going transapically for that. And, indeed, I understand that there are a number of new companies presented in Tel Aviv last week that are employing the transapical approach for this.

So I think that you will see these delivery systems. I think it is going to be replacement for functional MR and initially by a transapical approach.

David Erickson - *Edwards Lifesciences Corporation - VP, IR*

Wes?

Wes Pedersen - *Minneapolis Heart Institute/Abbott Northwestern Hospital - Interventional Cardiologist*

There is still -- you will still read a lot about indirect and direct annuloplasties and the transcatheter markets. And I think the indirect is the one that uses coronary sinus. It is easy so, therefore, it is attractive to a lot of people. But it is unpredictable and has risks and I don't think it is going to get there.

The other one is the direct and the best I can understand is it is obviously a very difficult -- the direct, they have not done, but it is a very difficult procedure and basically rolls you down to the [de vaca]. Would that be similar to say which the surgeons have gotten rid of. They know they need to put a stiff ring around it. And so I just don't see a future in those types of procedures. Valve replacement makes a lot of sense, to this huge group of patients, to me.

David Erickson - *Edwards Lifesciences Corporation - VP, IR*

And I am going to add, Don. And the cardiology we are spending a lot of time educating the cardiologist now through the college and other places on not only recognition of the two types of mitral disease, but when timing and how to get it at appropriate interventions.

Unidentified Participant

Which I think is going to be very important. Randy, Wes, and Mike, thanks a lot. We are actually going to open up questions to the audience. So (Conference Instructions). Also we have questions about the surgical business.

QUESTIONS AND ANSWERS

Unidentified Audience Member

(inaudible) just for the panelists, you did very nice job of narrowing down the opportunity. It sounds like I don't know if I am [paraphrasing it perfectly], but functional MR patients with maybe narrow ventricles, I guess the question having even that population, aortic, one of the things we came accustomed to is that on valve worked in a lot of very homogeneous patient population, but then that patient population described in mitral, functional and narrow ventricle, is that population homogeneous enough to see one valve treat a lot of patients? Or are we still going to see multiple valve pipes even in that patient population? And I have a quick follow-up.

Wes Pedersen - *Minneapolis Heart Institute/Abbott Northwestern Hospital - Interventional Cardiologist*

Mike, do you want to start and then Randy?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

I think the common denominator to that disease is annular dilatation. The diseases of the ventricle, it tethers the leaflets and as a result you get secondary annular dilatation. The surgical treatment of that, of the undersized annuloplasty is based upon overcorrecting that annular dilatation. But it doesn't change the disease of the ventricle. And that hence why replacement makes more sense than repair.

I think at this stage of knowledge and of technology, just getting one of these to work is sufficient enough. And I can't fathom if we are just talking about that functional MR, why you would need more than one design type to address that.

David Erickson - *Edwards Lifesciences Corporation - VP, IR*

Yes. I think you are exactly right. And I think Wes made an interesting point in -- not to try to bring back the degenerative form, but there are certain degenerative forms of the disease where a single valve would make a difference. But, I think Mike is exactly right. This is an annular disease and with a transapical approach, you can probably take care of this very nicely.

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

I think any valve, too, that you come out with has to get rid of peri-valves that are leak issues which is a problem. It is a complex structure the mitral valve [analysis] and you, also, as it sits down into the chordal apparatus. It can't distort those or pull those so that the functioning of the ventricle is impeded or create MR -- or MR on that basis.

And the third thing is, then, is a valve that, in order to compensate for the leak, pushes over underneath the aortic valve and blocks that. So those are three things that every person who is trying to make a valve needs to concentrate on.

Unidentified Audience Member

I just have a quick one, quick follow-up. Just on INTUITY really quickly. If you think about the positioning, given the heart team comp that becomes synonymous with EVEREST, the INTUITY positioning and pricing relative relative to transapical aortic and as you start moving into lower risk patient populations that they are surgical patients and you also have INTUITY, help us understand how you position those two products. Thank you.

Don Bobo - *Edwards Lifesciences Corporation - Corporate VP, Heart Valve Therapy*

It is a good question, David, and I will start by saying we probably are humble enough to believe we can fully sort that out. There will be patients in regions that physicians choose INTUITY because they are trying to do small incisions. There will be other places where transapical is a better answer.

I think we have actually gotten very comfortable with physicians making the choice. But it does come back to the evidence. The more evidence we are able to bring forward at launch I think the better informed they are in terms of picking which platform for which patient. INTUITY is in Europe. We get the CE Mark, the current version as well. It's approved broadly, similar to (inaudible) to [Magna East] so it really becomes physician's choice. Did that help?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

So, Don, I can add to that. So I don't think INTUITY is competitive with transapical. I think the question is where is the niche. And I think the niche for it is potentially minimally invasive aortic valve replacement. So it facilitates small incision surgery.

So the first question is, is minimally invasive aortic valve surgery better than maximally invasive aortic valve surgery. And there's a lot of clinicians that think so, but that hasn't been definitively proven.

And then, secondly, if it is better then you have to go through the same economic modeling that we went through with TAVR. Do these patients go home a day or two earlier? Do you spend less time in the operating room because it is a simpler operation? So that is the potential role for INTUITY.

Bruce?

Bruce Nudell - *Credit Suisse - Analyst*

Bruce Nudell from Credit Suisse. I have two questions. First is what are the one or two technical challenges that are really on top of the list with regards to mitral valve replacement through a transapical approach? Are we reasonably close? And the second one is, could you guys surmise as to the likelihood that solving MR or significantly diminishing it will assess, of course, heart failure in these functional patients?

Wes Pedersen - *Minneapolis Heart Institute/Abbott Northwestern Hospital - Interventional Cardiologist*

I think one of the biggest technological points that have just come to the forefront now is the 3D imaging. So these -- as opposed to an open surgical procedure where it is direct visualization, it is indirect visualization. And the explosion not only in 3D echo, but in image overlays. Multiple images coming together are going to make it a lot easier. And this is all part of the hybrid [broom] concept and so forth. So these things need to happen in parallel.

The other question was -- the other thing about mitral valve that's different than aortic valve is that when you break these things up and we looked at our data for acute MIs and primary PCA and the mortality is different for mild, moderate, severe and on worse. And that is different than AS, where, you know there are a few people that are replacing them early if you have LDH, but you wait till they get symptoms, so their heart fails and then you put in an aortic valve and you don't lose too much from it.

But there is going to be a lot of information we have to get out of that. There's a lot more variables to look at and I think we are going to be intervening earlier on those especially in the functional with heart failure.

Don Bobo - *Edwards Lifesciences Corporation - Corporate VP, Heart Valve Therapy*

Mike, do you want to address the functional MR and heart failure symptoms?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

Sure. First of all the two biggest challenges are anchoring securely and not obstructing left ventricular outflow tract either, because the anterior leaflet or because the valve is sitting below. So I think you'll see these valves sitting more in the atrium than in the ventricle.

And then the second is what are the chances that this is going to change the course of the disease? I am betting that it will. I do think it makes sense to will. I think that I don't know who those patients are yet. You can break fractional MR into ischemic and non-ischemic. I think it is going to work better in the ischemic disease than in the non-ischemic dilated cardiomyopathies, but I don't know that for sure.

So I am guessing that we will get smarter about figuring out who those patients are. I know I operated on some patients that 10 years later who are doing fine and other patients that are back in six months and I don't yet know how to separate those patients.

Don Bobo - *Edwards Lifesciences Corporation - Corporate VP, Heart Valve Therapy*

I think that as Wes alluded to, the advent of really super echocardiography and in the hybrid room or in the OR is going to make a lot of difference and because we do this it has been in my bag all my life but we are in there and with the mitral space, being able to look at things Mike is talking about is very important. And I think you have got to remember that, with MR as with AS, the disease -- the symptoms come late in the process of this disease especially with MR. The ventricle is being damaged, i.e., that means that your longevity and your quality of life is going down even though you may look good, your EF may look good and you may look good the atrium is being damaged so you are going to have afib and you are developing preliminary hypertension and irreversible changes on the right side.

So, this is a disease process as is AS that is deleteriously affecting the heart as it smolders along. And you are going to see an increased awareness of that process and in a new diagnostic way to tell which ventricle is being damaged early. I.e. we should intervene earlier.

David Erickson - *Edwards Lifesciences Corporation - VP, IR*

Very good. Mike.

Mike Weinstein - *JPMorgan - Analyst*

Sure. Mike Weinstein, JPMorgan. If I can ask a question for the panelists and then do a follow-up with Don, on a separate topic.

So there's a lot of challenges here on the mitral side and my question is really there isn't a good animal model, it seems. And so how do you know from the animal work that you can design a device for humans that doesn't extend into the LBOT, that doesn't interfere with the sub [mitral] apparatus. That means I can go down a list here of potential risks you started to touch on them, Mike, and how much confidence can you have going from the animal model to the human model because your risk are higher? Leakage is going to be a lot less well-tolerated on the mitral side that it was on the aortic side.

So how do you know going from animals into humans whether what you are going to run into (multiple speakers)?

Wes Pedersen - *Minneapolis Heart Institute/Abbott Northwestern Hospital - Interventional Cardiologist*

Animals -- yes, very different. I am going to let Mike handle most of this question. The nice thing about digilogic surgery or beating heart surgery is you can see what is going on at the time. And you don't come off pump and then take a look at it and then go back on and it is a long procedure. You sort of can tighten things up or move stuff over. Say, this is not the right device, I have got to pull it out, put in a smaller device in our something. And those are real advantages of these types of procedures.

I don't have the experience yet in putting these implants in. But that is a big concern but I think there are going to be certain patients where that will be a problem. But, I think it is going to be getting a size, given the size is right; learning how to size these [setups].

Mike, what's your experience been with them?

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

So, I agree with you might I think it is a huge jump to go from animals to humans and you can never really prototype it for sure and know exactly how it is going to translate. I think, in general, the sense of the feeling is it is going to be easier in humans than it is in animals for two reasons.

One is, you don't have good 3D echo in animals because of the relationship of the esophagus to the heart. And as Wes mentioned, 3D imaging is key for all this. I do have experience with a lot of the repair technologies both in animals and in humans in Europe. And I will tell you, the humans are much easier than the animals.

And then the second is that in the animal model the atrium and ventricles are very, very small. And the delivery is much more difficult. So when you get to larger dilated hearts with larger atrium and larger ventricles, it is only going to facilitate it. So my guess is it is going to be easier in humans than it is in animals, but until you actually make that leap and do it, it is total speculation.

The delivery part has been done as you know valve and valve through the (inaudible) micro stenosis or de novo. These -- or those are have more support, (inaudible) stretches and so forth, but so we can get there. The size of (inaudible) I think is going to be (inaudible).

Don Bobo - *Edwards Lifesciences Corporation - Corporate VP, Heart Valve Therapy*

Mike, your follow-up.

Mike Weinstein - *JPMorgan - Analyst*

Yes, then, Don. The transform trial you increased the size of that trial from 650 patients which is what you described last year to 950 patients.

So can you talk about why you did that and what changed in the assumptions on the (multiple speakers)?

Don Bobo - *Edwards Lifesciences Corporation - Corporate VP, Heart Valve Therapy*

Is that from clinicaltrials.gov? Is that where that 900 came from? Okay, so couple of things. One is we think we will exit this year probably over 300 so we are pleased with the enrollment of that trial. And because this is a registry kind of traditional heart valve trial, where you compare yourself to historical controls, we wanted to speed up enrollments. So we went to additional sites and to cover that you end up with an enrollment number that is bigger.

You have got some flexibility if you go to 650, 700. What you are trying to accumulate is experience at one-year patient years. And you can do that by doing a few and waiting a long time. You can enroll more patients and accelerate that first analysis point. So that is what that is about. I wouldn't get locked on 900 versus 650.

Mike Weinstein - *JPMorgan - Analyst*

And the reason why the enrollment is taking longer?

Wes Pedersen - *Minneapolis Heart Institute/Abbott Northwestern Hospital - Interventional Cardiologist*

To reflect back. Whenever you do these trials into 25, 30 centers it is a lot of work to get up and get running. Once centers get up I think the enrollment goes pretty well. I don't know, Mike, do you want to speak to that? You have been one of the top two enrollers.

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

Yes. So we have enrolled 52 at one of our centers and 15 at our other center. So we are the larger in rollers and that trial and it actually has been a much easier trial to enroll. Because we don't have to randomize against something else for it and the surgeons are pretty convinced that it is an easier operation to do.

So I don't -- haven't seen particular challenges to this compared to our TAVR trials. It is much easier to put patients in this trial.

Wes Pedersen - *Minneapolis Heart Institute/Abbott Northwestern Hospital - Interventional Cardiologist*

And we think we will finish enrollment next year.

David Erickson - *Edwards Lifesciences Corporation - VP, IR*

Thanks so much for your attention. I am getting the sign that we need to cut Randy, Mike, and Wes. Thanks a lot.

Michael Mack - *Baylor Health Care System - Medical Director, Cardiovascular Surgery*

Okay. I would like to introduce Carlyn Solomon who will talk to us about advancements in critical care.

Carlyn Solomon - *Edwards Lifesciences Corporation - Corporate Vice President, Critical Care and Vascular*

Thanks, Mike. A couple of months ago I was talking with a couple of analysts and one of the things one of them said they go through the usual Larry and Don talk through. Okay, what are we doing in heart valves. Next thing they say is, tell us about critical care. One says, I don't know that much about critical care and so, we go through the conversation about critical care and the other analyst said you know there may be some underappreciation of this business and value.

So I put a cheat sheet together for you here that, if you take one thing away this is probably the sheet to take it away on. And that is that we have a portfolio of solutions that are in a growth market that are growing around 3% to 6%.

Why is it growing? It is growing for two reasons.

First reason is, we have gold standard highly renowned brands that are growing primarily through geographic expansion. And the second reason is we have this market we have been developing for a number of years that I will get into more deeply called enhanced surgical recovery.

And if this story stopped there that is what the story would be. 70% market share in a market that is growing 3% to 6%.

On top of that, you get an option play on glucose. So Glucoclear is a product we talk to you a lot about. I'll give you an update today on where we stand with that. But, we are becoming very encouraged around this technology and the need for it.

So to talk to you a little bit about our platform. The new investments we have made have been around glucose and around this noninvasive technology which extends the enhanced surgical recovery market. And so we are very excited about our ability to help serve more patients and meet unmet patient needs with these products.

We have also divested a number of products. And in the last couple of divestitures, we haven't rolled those into our number. So although it has hurt our growth rate and that is some of the noise in the growth rate you'll see in critical care, we are convinced that we need to exit the nonstrategic assets.

And so, here is what the portfolio looks like going forward. We have these proven market-leading products, things like the Fogarty Catheter, the Swan-Ganz catheter that are expanding around the world. We have this enhanced surgical recovery phase which I am going to get into in more detail with you in a few moments. And then the glucose product line for in-hospital control of glucose in the hospital.

And we deliver all of this through our best-in-class channel. Nobody matches our channel into the spaces we play in and their best-in-class education programs. So let's talk a little bit about enhanced surgical recovery.

So here is the idea. Right -- during surgery if you don't get the right fluid at the right time it has an effect on mortality and it has an effect on complications. And you can be too dry or you can be too wet, and time matters. You need the right amount of fluid at the right time. And Dr. [Vaccaria], who is well-known for her work in patient safety and quality can say it better than I could ever say it. Fluid optimization enhances patient recovery.

And how does it do that? It enables patients to have lower wound infections, lower pulmonary complications and lower kidney complications after surgery.

And we estimate this market to be about $700 million. It is underpenetrated today, about $120 million is penetrated; and we hold the lion's share of that market at an 80% level. And I put the graphic on the bottom just so you can see we have been working at this for a number of years. We are largely developing this market. And you can see it has been growing at a 20% plus CAGR.

And it is picking up speed. I think the economic fire actually helps us in this market. Why? Because there have been more than 30 randomized controlled trials and numerous meta-analyses of these trials that shows that it reduces complications, it reduces morbidity; and as a result of that on average, you get a two-day length of stay reduction. And depending on how much hospitals value their bed days, that is greater than a $2,000 savings.

And as a result of all of this, the societies are coming in the line on it. The National Health Service now requires the patients be monitored and their fluid be optimized during surgery. You have this Enhanced Recovery After Surgery, which is an international group that meets and is developing and pushing this technology and more and more of the societies are coming on board.

It takes a team and a partnership approach to implement this. You have to have surgeons involved, you have to have anesthesiologists involved and they all have to be coordinating.

And perhaps the best way I can share with you how this is received out in the hospital space is to share a short video with you. You can queue the video please.

(video playing)

So, there you have it. You have Duke talking about this, you have folks in Europe talking about it, folks in the US. And they are implementing it. And we are at the forefront of that. One of the things our customers said they wanted was, hey, could you give us a noninvasive way to do this?

We think it would make sense to do this in [left-field] patients. And so as you know we purchased VMI. We are putting that on our installed product based and those products will come out this next year.

Our role in this because we are the leader in this area is to help the clinical societies implement this, to help with the evidence generation, the centers of excellence development and we also -- for hospitals because we run into this is just say, show me how to do it, how do I do it. So we have reconfigured our sales teams to focus on that and be able to deliver this into the marketplace and help hospitals increment this technology.

I would like to give you a quick update on GlucoClear.

So, what if you only saw this in your job? What if the stock came across kind of haphazardly stock prices, market movements, and this is all you saw. Would it change if instead of that you saw this? Would it enable your decision-making?

Well, in the life and death situation in hospitals, what they are seeing is those first stocks today. And they are not always accurate. So maybe you don't get a good accurate glucose reading. And for those of you who may be new to this field, I put the band up here because there is real patient risk when you go below that band and when you go above this band.

So this is real patient data. It is one of the few patients really ever studied. We are in -- have basically monitored hundreds of patients at this point to understand the glucose swings, the glucose levels, this is one such patient.

And what happens is with glucose control, if glucose drops too low, if it goes below 70 even, there's a mortality impact on patients. And the way they be control glucose in a hospital, they give IV insulin. So they need a very, very accurate reading.

On the other hand, if glucose levels go too high and particularly if they stay there for any length of time. In this hospital let's say above 120, you won't find a doctor who says you should go about 180. If that happens you are going to have increased complication rates. So what you can see is our device that we are just now launching in Europe is able to give this near-continuous status stream which lets them react to that and understand very clearly what they should do with the patient.

So, we have done a limited EU launch which has confirmed the need and, in fact, they don't control the glucose levels very effectively in their patients. And we are the first to market with this kind of technology.

Now one of things you might say is, hey, you guys have got a CE Mark, what is sales going to be? And this is what we told you we would do last year. Much like we did with INTUITY, we said because this is so new, brand-new market, brand-new opportunity, brand-new experience clinically, we need to develop the market in a very careful way.

So we have completed our product development. We are moving now into kind of a normal development. I would say the risk of can we do this is past. We did that since last year.

We have obtained a CE Mark and we have started to gain that real-world experience. This next year we are going to publish accuracy studies so exact accuracy as I said before is very very important. We will demonstrate that you can actually control glucose with this monitor's help and we will seek FDA approval. Full path to value creation is going to come once we are able to publish outcome data. That is when this thing will really take off.

So next year we are guiding to 3% to 6%. If I were you I would say, okay, over the last couple of years you haven't done that. Well, there's some noise in here. Some things you ought to know.

Number one, you guys are following and every time we do a quarterly update we have talked to you about China. Well, we are going to lap China here at the beginning of 2014.

Second thing is we have been getting out of these businesses. We haven't been culling them out as discontinued and they have impacted our results. So we will have one more year of that with [Actest] and then you are in this range. Now next year in addition to those things we are going to have the benefit of a new product which is going to add to our growth rate with our noninvasive ClearSight product.

So here are the things you should look for from us. In Q2 we should release another algorithm update for flow track. We should in Q2 and Q3 be able to get ClearSight on our EV1000 platform. Again that is a noninvasive monitor, and in Q2, we will have our accuracy study published, the results of that, and begin enrollment on our outcome study by the end of the year.

So in summary, take away critical care, what is the value? We play in markets and have a 70% share in markets of 3% to 6% growth. And GlucoClear is a breakout opportunity and potential. Thank you very much.

Tom Abate - *Edwards Lifesciences Corporation - Corporate VP and CFO*

Okay. Financials. If you come to our conference on a regular basis, you know that we always like to start the conference out with two steps. One is to reaffirm our guidance. And possible -- I am very pleased to say that we are in a position today to reaffirm the guidance that we gave you in October.

Secondly, we like to look back and say every year I recognize that I put out a goal, and just the credibility of coming back and saying, let's remember what we said a year ago. The primary difference is $100 million of sales on our target, which is approximately 5%, of the $130 million was a harder FX headwind than we had anticipated. The remaining $70 million was to the businesses.

That lack of mix -- that little bit of sales was primarily the reason that we took down gross profit by about 50 basis points. It was due to mix. And the free cash flow and EPS all fell from that difference in sales.

Before I talk about 2014, I just wanted to give you a little bit of heads up. When Larry was up here and Mike talked about aggressively competing, one of the things we are trying to do is bring the new products as quickly as possible to patients.

So what that means is, in SAPIEN 3 and XT, today we are selling product that may have -- may end up being in the future swapped out. And the accounting rules for that require us to book a reserve. So at the end of the year, depending on what we believe, it will be based on our estimates of approval dates and so forth. For SAPIEN 3 we expect at the end of the year, so certainly there will be some reserve here. And it will be a requirement to reverse sales.

Now, these sales are returned in total when the actual swap occurs. So the amount of the swap all of these sales come back. So it is not any real economic impact. It is just a year-over-year timing of that reporting. But it could throw off the numbers a little bit. I gave you an estimate, but they are going to fluctuate considerably based upon our expectations at that time.

Now, it is -- associated with it is a real inventory reserve which says that we do fully expect that some of these products will not have enough life left on the product. It won't have a home, particularly the SAPIEN product, that we would be able to use it. So there will be an anticipated charge at that time related to inventory that we expect to obsolete.

Realignment reserve -- there are a number of minor things in here. The largest piece of this is where we made an effort in Carlyn's business to be more efficient. Primarily in the Caribbean we made some changes and we are anticipating a severance -- almost entirely severance charge that goes along with that.

So with that, let's jump into 2014. Here are the targets for 2014. If there is something you should take away, I think we should have driven it home by now, but I will drive it home four more times in my time. And that is, it is a wide range of possibilities. Okay?

What we tried to give you is our best estimate -- our most realistic estimate, and rather than punt on this and not provide guidance, we thought it was helpful, it was instructive to say, you need to recognize there's variables that are outside of our control, primarily the approvals of new products that could affect this. So you should expect a wide range.

We also would say at the same time, as soon as these things come into place, that you could expect that we would tighten up these ranges and would get back to normal reporting. But, for now, we wanted to give you a midpoint of what our models are telling us on EPS. Free cash flow, we gave you a wide range and GPS -- on sort of GP. But I will cover all of these. Each of them have an individual slide.

First, let me start out with EPS. To be very quick -- to be very clear, I wanted to break the components to what they're specifically driving, what is essentially a flat earnings prediction for next year. A range around $3 is an end result, but with a wide range, and the difference or the variability coming from the first column, which says all of the competitive issues are wrapped in there.

How aggressively the competitor starts. How we respond. And about $100 million, $120 million of underlying growth, we expect the improvement, which is a reasonable return on EPS of $0.23.

After that, and it is operational, but I have excluded just for illustrative purposes that the SAPIEN valve today is a more expensive valve to manufacture. We have a program directed directly at reducing the cost of this valve, but it is not something that is going to change overnight. We would expect an improvement in the future, and I will talk a little bit about it in GP also.

But it is something that affects the decision that says, go early, go hard, make this widely available. There is a cost to that decision. And that is about 100 basis points also in GP.

Incentive compensation represents that the incentives in the Company are very closely tied to our financial results. So on the first slide, you saw that we reduced our EPS early in the year to $0.21. There was a financial consequence because they are based on sales growth, cash flow, and EPS. So year-over-year, what that means is in 2013 there was less compensation expense that needs to be replaced in 2014.

Foreign exchange, it is the EPS impact. What primarily happen here, where we don't typically see this big of a difference, is it was driven by the yen movement. We had very favorable contracts.

I talked about it every quarter, tried to give you guys an idea of what was in there. But we were benefiting from those contracts. I don't go too far out. So, at any point in time, those contracts next year give us some benefit for the yen, but it is less than half of what we saw this year.

I probably should put interest and shares together because the $600 million debt bond that we issued, we use $200 million of that to offset the cost of interest. But that was already done this year, so on a year-over-year, I just broke the two pieces. And the share repurchase assumption is essentially our normal repurchase, which is what we give you for modeling purposes.

It is not a commitment, but I know you guys need shares and we come in -- typically what we will do, as we will spend about our free cash flow. Now, this is a little bit less, but it is also a little bit weighted in the front half of the year. So there is an impact year-over-year. And that is how we derive our overall midpoint.

I will go through all of the businesses individually. You see the variability I just mentioned at this point, surgical heart valves and critical care. Pretty tight ranges, pretty much what we always expected, so the variability exists primarily in the transcatheter. And that carries through on our overall growth rate.

Underlying surgical valves: John has showed you -- I hope you saw -- and you guys have followed the last few quarters. While the CAGR is 3%, this range -- lately Don has already been well within this range within the last couple of quarters.

And what we are projecting for Q4 says we are here, we are growing slightly better than the market do due to his investments in pipeline and evidence development. Maybe more particularly on the INTUITY product, I think, picks up an extra point even over last year. So a reasonable growth considering where he is at today.

For THV, I just want to remind you of all of the things that Larry said. Normally, we do not give out this much for modeling, but we know this was a pivotal year and we just wanted you to understand what our assumptions were. Now, they were both very aggressive for the competitor, but it was also very aggressive for us and our response.

And, particularly, you need to take note of the net stocking: very different from what we originally thought. We are accelerating this. We are going to move fast due to the new products. That has a cost to it. It is much higher.

We would have thought that this was more an even number for this year, a year ago, but this is the way it looks like it is going to play out. We were always going to give these credits, so it is just a matter of timing. Whenever we did stocking, as long as customers came up, those sales were going to reverse. There are more of them in 2014 than we would have anticipated.

So that leads to the transcatheter, and here is the why portion. Primarily, the growth here in our assumptions is coming from Japan, lower than what we were expected to. But we always knew a year of competition was coming, if you look back on the various layers of growth that we put out for the years.

When we saw competition in the US, seeing that we had in an exclusive market, that we were going to experience a year of lower growth. And we are also experiencing, at the same time, the same issue with a couple of new competitors in Europe.

Critical Care guidance, I think Carlyn did a nice job of demonstrating that while recently, as rates have been lower, if we factor -- we take out a couple of factors that are primarily behind us, that he is well within his range. This would be a continuation of the success that he has driven in Critical Care.

All of those together, if I use the midpoint, I referred to this briefly is, if I just take midpoints -- and you know there is ranges, that implies $120 million of growth from the business. That is using the growth rates I gave you. And we are expecting about $20 million of foreign exchange that is going to be a headwind here. And that is [out our] $100 million increase.

Gross profit margin is lower by about 150 basis points of what we are expecting for this year; not that different. It is about 100 basis points off of Q4. But earlier in the year, we were at higher rates due to foreign-exchange.

So this slide should help you walk through foreign-exchange 2013 versus 2014 now. So 2012 is history. We are going to have less benefit in our hedge agreements, so we drop about 80 to 100 basis points on FX.

As you know, this is just assuming today's rates. If rates change, this number will certainly change during the course of the year. So I would like to break that out.

The other thing I would like to break out for you is product mix and say, well, just tell us about the business. Tell us about the sales, the pricing, and how mix is driving. The $100 million that I had on the earlier slide drives about 50 points of positive mix. And everything else is in the middle, primarily driven by the SAPIEN 3 cost increase.

R&D, we will grow R&D pretty much consistent with what we are assuming is the midpoint of our sales. So as a percentage of sales, it is not coming down.

When I look at this -- when I particularly reflect on how much we spend and what we get out of the pipeline, and hopefully that is what today is all about, and you are just as impressed as I am on the product set we have produced and where we are and that we are leaders in the field. And so, therefore, I feel very comfortable how we are investing in R&D.

We did not choose to continue to provide SG&A leverage. We thought, in a year where we face competition in major markets, that this wasn't the year to retrench. So I think Mike mentioned it already in his opening that we are going big, and the idea is to continue to support. We think that adds more value than trying to drive this down in this particular year.

You see, we were on a trend -- an impressive trend. We actually, in the middle here, we also aid a med device tax. So we know how to do this. It is just this year wasn't the year that we felt that was the best strategy for future shareholder value.

A few miscellaneous assumptions. The interest goes with the bond, I already mentioned. Tax rate is benefiting EPS. It is about two percentage points below this year, and it is just a reflection of our success at strategic product sourcing and where we manufacture and where we operate. We are very fortunate and we are very happy to see that these strategies are paying off in a real way.

On shares, it was interesting. I reflected back to a year ago. I was projecting and, at the time, we were 118 million shares. So this projected for this year is a full 10 million shares better than when I stood here one year ago.

And before I close, I just wanted to mention that we are very active in litigation. There is definitely activity going on. We have repressed an injunction.

We have requested additional damages in the Anderson case. That decision is pending at the Delaware courts and we are confident that we are going to see an extension on those patents till March 2016. None of that has changed, as well as the enforcement of Cribier and Spenser in the US and Germany.

But the financial results I have given you, there is no benefit assumed in any way from litigation. And we thought that was the best way to keep things clean rather than to bake it into numbers when it is uncertain. Litigation is almost as uncertain as regulatory approvals, and we will wait and see. But it would represent a potential upside to everything I have shown you.

And with that, I just wanted to give you a reflection here on recent EPS over the last few years. And then just a reminder that the $3 is the midpoint of what we are expecting today, and I would expect in the near future that we are going to be updating you and giving you a range at some point, once some of the variability comes out.

And, with that, I think we move on to Q&A. Oh, I'm sorry. Closing remarks.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman, CEO*

Thanks. So, let me bring it home and then just summarize. You know, Edwards operates differently than most other companies in our space. We have a differentiated strategy, and it really is around focused innovation.

We believe that innovation in our space is rewarded. We think people are in serious need of these innovations and we think when we do that successfully, we are able to drive outsize sales growth.

We are fortunate to be building on our leadership position. We have very strong positions where if we don't do a lot of things -- we only do a couple of things, and the things we do we try to be the best at that. What distinguishes us and what builds loyalty is the fact that we have best in class products.

If you wander around and talk to Edwards employees and ask if they ever really need having a product that Edwards provided, they would insist that it be the Edwards product. We have a tremendous amount of pride and confidence in everything that we produce. And we think that underpins our leadership.

We continue to be aggressive investors in our future. Just to remind you of some of the investments we have made in the recent past -- and it is at a time when most of our competitors actually are slashing costs and reducing their organization. We have had the opportunity to be builders.

We have had the opportunity to build a world-class interventional franchise focused directly at structural heart disease. We have had a chance to add tremendous technical talent to our Company. We have been recruiting in the best engineering schools at the same time when others just weren't.

We have been building our quality system and our operations infrastructure to support this future growth that is coming, and we have been funding aggressively our advanced technologies. I am not going to talk deeply about that one, but we have a number of opportunities in that space.

Just to give you some sense of this, to be a little bit tangible, we have an awful lot of invention records that get created within Edwards Life-sciences just in the past few years -- two, three years. We have more than 700 issued patents around the world and about half of those are US issued patents, and many more in the pipeline. Gives you a sense for what we have got coming in our investment in the future.

If you had asked yourself where is the growth going to come from for Edwards in the future, on a long-term basis, where does it come from? Well, it is on multiple fronts, but it is going to be driven by our innovation.

First of all, we think we have multiple growth opportunities within THV. THV is just not going to grow between now and 2019. It is going to grow for a very long time. Why? We believe there is expanded indications and that device innovations are going to keep driving this to be used by more and more patients.

And we think these new opportunities like mitral valve disease are substantial. We believe that valve surgery, although it is wonderful surgery, needs to be less invasive, and that we have tools to make that less invasive, which is really desired by patients and their physicians. And that we are going to have opportunities for younger patients than ever before.

In Critical Care, we believe that our new noninvasive technology is going to allow us to implement more and more of that enhanced surgical recovery that is going to be real savings and real benefits to hospitals and the patients that they serve. We believe that GlucoClear is an exciting opportunity that we have a differentiated opportunity there.

And, finally, emerging markets are just now getting wealthy enough that they're -- are able to afford Edwards products more than they ever have in the past, and it is a real opportunity. So multiple opportunities for us to grow, mostly driven by innovation.

Now, let me switch gears and talk about mitral valve disease, because you have just gotten a little bit of an education on that. I know many of you already know a lot about mitral valve disease. We have been at this for a while.

We have been pioneers in the treatment of mitral valve disease for literally decades. This is not something that is new to us. We pioneered repair. We pioneered many interventional technologies along the way.

Our interventional work in aortic disease has allowed us to have access to really the thought leaders around the world -- cardiologists, surgeons, and many other inventors. We have a complete array of the technologies that you will need to treat this mitral valve disease through an interventional system, and we have been making into the investments for a long time. We have got more than a decade of investments in interventional treatment for mitral valve disease and we have dedicated teams that are pursuing multiple platforms.

So where are we today? I stood here one year ago and said it was likely that in 2013 we would have one of our mitral transcatheter interventions make it to first in man. And I am proud to say that we are on track to do that.

Well, what has been going on for the past year? Well, an awful lot, and I don't know if people have a full appreciation. I asked our team to just give me a little list here than I could share with you, just so you get a sense for what goes on.

There is a loop that goes on, if you will, when we create designs and then we test for those designs in benchtop tests and then animal tests. And that went on for quite a while. But when we finally get a design, which we have one which we really like -- a transcatheter mitral valve replacement product -- then we start that path -- a serious path toward first in man.

And we know a lot about boundary conditions because of our past experience. So we do a deep amount of testing and evaluation on valve sizing, on valve durability. We do a lot of AWT testing, hemodynamic testing, the microbiology, biology, and chemistry testing associated with it; a lot of work on frame durability, frame corrosion, boundary conditions determination, frame finite element analysis, shelf life testing, calcification studies, and then we move to first acute and then chronic animals.

We need green lights on every one of those steps or we don't go forward to the first in man, and I am pleased to say we have gotten the green light on each one of those steps. We also had to go through those processes for our delivery systems, our crimping systems, and the dilator kit.

So here we are today, pleased to be where we are. Just to tell you a little bit about it, and my apologies for the image looking kind of shady; that is purposeful. We really didn't want to disclose too much detail about the valve design itself for competitive reasons.

But we believe that this valve replacement has the opportunity to address multiple etiologies. In other words, we think it has an opportunity to address both functional and degenerative disease.

We have worked hard to have a system to minimize paravalvular leak, which will be very important. It is a self-expanding design that has a unique anchoring approach. And anchoring is one of the most serious challenges here.

We are using our GLX bovine pericardial tissue. We think this is awfully important. Remember, this is a high pressure application that has an opportunity for advanced calcification to be able to use our best durability tissue treatment, we think is very important.

Right now, this is a very large profile, which will require transapical delivery. We really did not want to slow down the development of what we are going to learn in the first in man experience by optimizing that at this point. And this describes really where we are with the first in man mitral transcatheter heart valve.

Now, what do we look for? How do we decide whether we have success or not? Well, just wanted to share some of our own design requirements.

In the early stage, we are obviously going to be looking for secure attachment. We're going to be looking for how well do we resolve mitral regurgitation. We are going to look at that procedure and decide whether it feels predictable and reproducible.

We are more going to focus on a 30-day outcome. We don't feel like you walk away and an hour later or a day later that you really know how well you have done. We are going to be evaluating the stability of that implant over the first 30 days as most important.

It is also the kind of therapy where you are going to be quite interested in the mid- to late-term clinical results. It is not obvious that if you get a great early result that you will get a great late result. You're going to be looking for symptom improvement; again, have that durable leak performance and durable results that go along with that.

So our plan is very simply to capture those learnings from first in human and try and do that. And then, at the same time, we have a team that is working on decreasing the profile size, enhancing ease of use. But the learnings have come from first in human and, as was described earlier by Dr. Martin, it is a big step to go from animals to human and we expect to learn quite a bit in that process.

So in particular, we have our first patient that is planned for this month. I -- don't expect necessarily to see a press release when we do the first patient, because we are not sure that that is really the important step. Expect us to update our results when we deliver our Q4 results in early February.

These are real patients that are involved and we think that really understanding this deeply is what is most important to us. No one has successfully done in implantation of a -- or a percutaneous or transcatheter mitral valve replacement in the past, and so this is serious business and we treat it that way.

If we get favorable results, the physicians are going to be encouraged to continue. And it is really going to be their decision on whether they continue to do patients or not. But if we get that, our intention would be to do a whole series of first in human. And you would hear the results of that series reported at upcoming clinical meetings.

So just to summarize, and you have heard this already, the mitral opportunity is large. Even with today's guidelines, people are not treated nearly at the level that guidelines suggest, let alone if you had a catheter-based option.

Without treatment, you heard Dr. Martin say, the prognosis is very poor. The longer you wait, the worse your prognosis is. Replacement therapy really does have an opportunity to step on a number of patients. We will have to see if that bears out.

Imagine that early on that we will be treating the highest risk patients and then moving and progressing beyond that. And mitral disease, as you know, is more prevalent in aortic disease. So the opportunity is quite large.

So just to summarize, we have a lot of shots on goal. We have got a lot of new products in the pipeline. I think these are well described during the course of the day.

The only thing we didn't talk about really were the advanced technologies. And we don't do that for competitive reasons. But we have some interesting things cooking in there as well that we look forward to bringing all of these forward for you, and they have real opportunities to enhance value.

Just to be more specific, you should expect regular press releases during 2014, certainly the big things like the launch of XT and SAPIEN 3, but also progress on CENTERA valve within transcatheter heart valves. You will see exciting progress, I think, from both INTUITY and GLX as we complete enrollment of these trials and move forward.

And in Critical Care, you will see our ClearSight technology being launched in the US, in Europe on Edwards' premium platform and more progress on GlucoClear.

EXHIBIT C

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

EW - Edwards Lifesciences at Cardiovascular Research Foundation (TCT) Transcatheter Cardiovascular Therapeutics Conference

EVENT DATE/TIME: OCTOBER 31, 2013 / 2:00PM GMT

CORPORATE PARTICIPANTS

David Erickson *Edwards Lifesciences Corporation - VP of IR*

Mike Mussallem *Edwards Lifesciences Corporation - Chairman and CEO*

Larry Wood *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Tom Abate *Edwards Lifesciences Corporation - Corporate VP, CFO*

CONFERENCE CALL PARTICIPANTS

David Lewis *Morgan Stanley - Analyst*

David Roman *Goldman Sachs - Analyst*

Larry Biegelsen *Wells Fargo Securities - Analyst*

Rick Wise *Stifel Nicolaus - Analyst*

Kevin Kotler *Broadfin Capital - Analyst*

Jason Mills *Canaccord Genuity - Analyst*

Bruce Nudell *Credit Suisse - Analyst*

Kristen Stewart *Deutsche Bank - Analyst*

Matt Taylor *Barclays Capital - Analyst*

Danielle Antalffy *Leerink Swann - Analyst*

PRESENTATION

David Erickson - *Edwards Lifesciences Corporation - VP of IR*

Good morning. I'm David Erickson, Vice President of Investor Relations for Edwards Lifesciences. And I'd like to welcome you, and thank you for joining us today. Before we get started, let me take care of the housekeeping items. This meeting is being webcast live, and will be archived on our website at edwards.com. During the meeting, the management of Edwards Lifesciences may make forward-looking statements that are based on estimates, assumptions, and projections. These statements speak only as of today. We do not undertake any obligation to update them after today.

Although we believe them to be reasonable, these statements involve risks and uncertainties that could cause actual results or experiences to differ materially from the forward-looking statements and information concerning factors that could cause these differences may be found in our earnings press release, our annual report on Form 10-K for the year ended December 31, 2012, and our other SEC filings which are available on our website at edwards.com.

So that we don't interfere with other sessions at the conference, we plan to keep the formal portion of today's meeting to 20, 30 minutes, give or take. And the webcast will conclude at that time. So that everyone has a chance to participate, if you're called on, please limit yourself to one question plus a follow-up question, and also please state your name and company before asking your question.

Representing Edwards management are Mike Mussallem, Chairman and CEO; Tom Abate, CFO; and Larry Wood, Corporate Vice President, Transcatheter Heart Valves.

And with that, I'll turn it over to Mike.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Okay. Good morning, folks. Welcome. Nice to have you here. Let's keep this informal. There's no really prepared remarks to start out. I think we've all had a pretty rich week of new data and information at TCT.

And I think we'll just throw it open to questions at this point.

Dave?

QUESTIONS AND ANSWERS

David Lewis - *Morgan Stanley - Analyst*

David Lewis of Morgan Stanley. Maybe just a first question, Mike, I think the big surprise, additional to the data, was the timing and the decision for the FDA to not require a panel for the Medtronic CoreValve. And you did talk about a couple of days ago, the timing of your expectations for XT in mid-2014. Maybe just talk about what you know about, obviously, your trial versus CoreValve and the modular submission; and any insight you could provide to us maybe since the call, in the strategy for Medtronic being able to come to market with CoreValve prior to XT; and some of the efforts you may have underway with the FDA to perhaps accelerate that timeline from mid-2014.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Yes. I'm happy to -- it's a broad subject. I'm happy to jump into it and let Larry jump in, as well. Broadly, you'd say the results of the trial were quite good. This is giving credit for just a remarkable trial. The results are as good as anything that we've seen from CoreValve. I guess if there was a surprise in it at all was that the timing. So the timing really looked like it pulled forward from what we had anticipated in the past. And, as we've discussed in the past, the sales in 2014 is going to probably be impacted by the introductions of safety in XT, versus when CoreValve is introduced. And now it looks like CoreValve is going to come earlier.

Now, exactly when Edwards comes to market versus CoreValve is a great question. I don't think we have any particular insight on that. This is in the hands of the FDA, so tough for me to comment on that. But broadly, I think what just happened is the inevitable competition that was going to come to the US -- it looks like it's going to come sooner than what we thought before.

David Lewis - *Morgan Stanley - Analyst*

For you, Larry -- maybe the Street is of the view that a six-month advantage of getting XT out before CoreValve is important. Because you'd have the advantage on lowered French size and really could be a nice, competitive, kind of encounter detailing, but getting in front of your competitors. Are we overestimating the impact of that six months?

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

I don't know. I think the fact that we've already trained all of our sites; we know from our European launch the conversion from SAPIEN to XT went very, very quickly. I think we converted almost all of our transfemoral customers within really a matter of a couple of months. So that process goes very quickly, and it's much, much faster than starting people from scratch. So, I think once we get the XT approval, I think we'll be able to move very, very quickly to convert all of our customers.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

David.

David Roman - *Goldman Sachs - Analyst*

Thank you. David Roman from Goldman Sachs. At the Medtronic Analyst Meeting that they hosted the other day, physicians indicated a view that there was no reason why market share in the United States would not fall out similar to what we've seen in Europe. Can you maybe just give us your thoughts on how the European experience versus the US market -- how that might differ? And why or why not a 50-50 split is a reasonable assumption?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Yes, I might start out, and welcome Larry to jump in as well. The situation in Europe was a little different. Remember that CoreValve probably was introduced -- as a matter fact, it may be even a few months before the SAPIEN valve -- but, largely, they were introduced at the same time. Then you so had CoreValve and 18 French system, and SAPIEN at a 24 French system, when they were initially launched.

And the market share split around 50-50, but the Edwards market share was transapical and transfemoral, so there was a large difference. Much more of the transfemoral was CoreValve initially. And CoreValve, I think, in those early days would have focused purely on cardiologists. There was really less of a heart team as part of their approach. And so as we come into the US, very different situations. There's been a lot of maturity since that time. Heart teams are in place, and a lot has changed.

So when SAPIEN XT came, there was a pretty significant share shift on the transfemoral side. And I don't know if it's 50-50 right now; we could get into that debate, exactly where market share is, but transfemoral has moved pretty dramatically. We believe that Edward sells maybe equal, if not more, transfemoral than Medtronic does. And so you've watched that change pretty dramatically over time, with the advent of the SAPIEN XT. And that performance of SAPIEN XT has continued to do well.

You've seen our results reported over just the past year. The growth of transfemoral has been pretty remarkable. It's been strong double-digits, so we sort of like the way that we compete with a transfemoral system. And, again, transapical is one of those -- or even TAA -- is one of those that, at this point, they really don't have an approved system when they probably first introduced. So there's going to be some peculiarities of the US launch, or not exactly the same in Europe. Although I'd say the Europe experience was not a bad one to look at to take your cues on how market share might go.

Tom Abate - *Edwards Lifesciences Corporation - Corporate VP, CFO*

Was it a couple of years, Larry, before we saw TA in Europe?

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

TA came shortly after TF. It came about three months later. But we had our 24 French system for a couple of years in Europe before the 18 French system came in. And so the competitive dynamics were pretty different.

Tom Abate - *Edwards Lifesciences Corporation - Corporate VP, CFO*

I'm sorry. I meant the XT. There was a while where we (multiple speakers). The timing here being much, much closer; and at that point, 18 French versus -- was a big difference.

David Roman - *Goldman Sachs - Analyst*

And I guess what my follow would be, you've had a very deliberate approach to the launch. I know that outcomes have been a big focus, and my understanding is that your sales reps do get compensated to some degree on outcomes. But as you look back on the launch, have you squandered in some way the two-year lead that you've had versus Medtronic, in not being more aggressive in either patient education or direct-to-consumer marketing? And is there anything that you plan to do to accelerate your efforts to build your presence before Medtronic comes in here, when you're going to be competing against a company whose core competency is really market building and sales.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Thanks, David. When we look back, we are proud of the way we introduced. We think there was nothing more important than us to just get great procedural results. And so that focus -- you can argue with that. At this point we're sitting here having transcatheter heart valves being a very well-respected procedure that people look at as the new standard to practice medicine. Now, should we, or could we, have developed the market more aggressively? I suppose that's true, and we're certainly engaged in that in a bigger way in 2013.

But the other way to look at this is, to give Medtronic credit, they are very good at developing markets, and we welcome having them be part of it. One of the things that goes along with being the only company in the space -- we're the only ones developing the market. And to have two companies do it, especially a well-respected company like Medtronic, I think is only helpful for those patients that are untreated.

Yes, Larry.

Larry Biegelsen - *Wells Fargo Securities - Analyst*

Thanks. Larry Biegelsen, Wells Fargo. I have two patent questions and one strategic question. So, Mike, I was surprised by the Street reaction to the CoreValve launch being pulled forward by eight months. Because they had to pay damages and lost profits through April 2010, I believe, because they infringe on the Andersen patent which should be valid until March 2016.

So my question is, while the odds of an injunction are low in the US, do you think the worst-case scenario is they will have to pay you for lost profits through March 2016 if they launch at risk in the US?

And the second patent question is, why did you wait until the European Patent Office opinion was issued before posting the bond in Germany? And after your answer, I have just one strategic question.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Okay, thanks. Yes, in the US, I think you -- I think we have pretty well chronicled what's gone on there. We thought there was a pretty decisive win in the court that goes back on just three or four years ago now. And then the appellate court upheld it strongly just a year ago. And we're looking forward to the judge actually offering up an opinion. Yes, we think that we are clearly owed damages. We think they are substantial. And we think that those should remain in place until the patent expires. And we believe that there is a likelihood that the patent will be extended into March of 2016. So all of those questions is consistent with our own belief.

But, again, we're waiting for the court to ask. It's a very busy court, but we're hoping that they act here sooner than later. It could happen, I suppose, at any time.

In terms of what's going on in Germany, we thought it was a pretty decisive action on the part of the court. And even though the European Patent Office just found this week -- or, they didn't find, but they offered a preliminary view that the Spenser patent was not valid. We didn't expect that to be the case. We don't agree with that, and we're going to petition that.

But we -- as we were proceeding forward, that we were going to implement the injunction. So, I think as we indicated, we really haven't factored any results from the injunction into our Q4 results. And then based on this preliminary ruling, I would say it calls into question whether the injunction is really going to stick in 2014. So I would say we're going to consider it an upside to 2014 in our own plans.

Larry Biegelsen - *Wells Fargo Securities - Analyst*

On the strategic side, so the mechanical circulatory support market has made great progress since you exited it in 2000. There's tremendous overlap between valves and VAD [surgid]. But both TAVI and LVAD, the AVAD markets has great long-term potential, but they're lumpy and competitive. So it would seem that having a presence in both markets would diversify your business and smooth out the performance. So my question is, would you consider diversifying your business and reentering the mechanical circulatory support market?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Yes, it's a pretty big question, Larry. As you might imagine, we're not going to comment on anything like that in terms of what our future plans would be. You know we're pretty focused guys. There are things that we think we are pretty good at. That is a great market that looks like it's going to grow for many years to come, but that's not one that that we have any kind of comments on.

Rick?

Rick Wise - *Stifel Nicolaus - Analyst*

Rick Wise, Stifel. One of the questions I'm trying to understand better -- and maybe, Larry, this is for you. We've heard Dr. [Mack] on Sunday talk about in the registry suggesting plateauing interests -- plateauing procedures. Obviously you won't bend before a quarter sort of growth. But just add totally about -- I've talked to doctors this week. I'm hearing more of the same -- volumes plateauing. What should we understand about the market enhancing at this point? Have we plateaued? Are we flowing? Is Medtronic actually, ironically, going to expand the market (inaudible) as Mike was suggesting? How do we think about this question?

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Yes. I think Mike's comments about having a second competitor in the field helping develop the market, I think are largely true. I think when XT gets approved and the availability of an 18 French system, I think it not only makes the patient screening process easier, but I also think it makes the economics of the procedure probably improve. You'll have more percutaneous access; you'll have less surgical close; you'll probably have shorter lengths of stay. And I think those are the areas that we really focus on a lot, is how would we work with the sites to better improve their economics over time. And that's where we spend a lot of our time with the program.

And I think those things all help it grow. We still continue to add centers. And I think the entry of patient population is still quite large. So I think one thing -- and I think when the TVT slides were shown later in the week here at TCT -- you'll notice that they put a lot of caveats on there. The VA system isn't included; the Kaiser system isn't included. It's a lagging indicator because sites take time to come up; sites take time to enter their data. So I think you have to be pretty cautionary about using the TVT data as some sort of gauger predictor.

Rick Wise - *Stifel Nicolaus - Analyst*

So, just as a follow-up, another thing I'm leaving and looking at competition on is this whole commercial clinical nexus we're looking at to 2014. Virtually every doctor I've talked to says CoreValve is going to take all the checks. Oh, no. We've got to take (inaudible) our equipment, all our patients. How do we think about this commercial clinical mix as we're looking into 2014? And -- I don't even know how to think about it from a modeling perspective. Tom, maybe as a last-time gesture, you can help us think about 2014 growth rates in this mix, and how that's going to affect mix? Thank you. (laughter)

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Larry, why don't you start -- maybe you could start with a comment on the clinical question there.

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Well, I think as a last-time gesture, I would do that. I think the question is a -- I think -- we try to get the positioning to prioritize doing clinical patients versus doing commercial cases. Yes, we do. We actually charge slightly less in our clinical, because we always want to make sure we're enrolling our clinical trial. SAPIEN 3 is obviously a big part of our leadership strategy. We've got done live cases here, if you've seen those live cases, or if you talk to our physicians who have used SAPIEN 3, I think people are exceedingly positive about the potential of that platform.

So, we really want to enroll that trial as briskly as we can, and move that technology forward into the US market. We have the approval right now for the inoperable -- or high-risk, rather -- inoperable and high-risk for SAPIEN 3, but we also want to bring SAPIEN 3 to an intermediate risk trial as well. We don't have anything more to comment, anything with timing or size of that trial, because those are still details to work out with the agency. But we expect that trial to be going on in 2014 as well.

Tom Abate - *Edwards Lifesciences Corporation - Corporate VP, CFO*

And there will be a trade-off of patients between clinical and, as you referring it, commercial. Because SAPIEN 3 will be coming into the same population, so I think the differentiation in sales between the two categories is going to blur, particularly when the clinical trial goes.

Rick Wise - *Stifel Nicolaus - Analyst*

(Inaudible -- microphone inaccessible)

Tom Abate - *Edwards Lifesciences Corporation - Corporate VP, CFO*

In 2014. Rick, I made it this far. I don't want to go out that way.

Unidentified Audience Member

Thank you. Just two questions on the data that Medtronic presented. The PVR rate that got better over time certainly attracted a lot of attention. I'm curious if you have any thoughts on that that we haven't seen anywhere else. And also, a 22% pacemaker dependency rate at one month seems to have been glossed over quite a bit by the Medtronic folks, obviously. And I'm curious if you had any thoughts about whether that's actually going to resonate in the clinical community.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Yes, I'll ask Larry to comment on that, in particular. The pacemaker rate is high, and it's certainly much different than the SAPIEN data. I don't know -- you guys can be the judge of how consistent that is with the European experience. Broadly, you'd say that it was an incredibly well-run trial. Really, I give them credit. This was -- I think they really maximized their results. The results are as good as anything that we've seen from CoreValve in Europe, and sort of best-in-class. It looks like it was a very carefully studied, very heavily proctored; so, just an incredible job. And you give them credit for running a spectacular trial.

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Yes, the point you raised on the PV leak rate, your comment is probably the most appropriate one. That's a phenomenon we've never seen before. Physiologically, why a PV leak rate would change after 30 days -- I can't explain it. I don't know why that would be the case. And it's a phenomenon that we've never seen in any of the European data or anyplace else, so it's something new. And I don't know that I would be able to understand it.

I think Mike's comments are right, though. I think they were very diligent about patient selection. I think they were very diligent about proctoring, and did that extensively in the trial. And I think they really did maximize their outcomes in this trial.

Unidentified Audience Member

(Inaudible -- microphone inaccessible)

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

I think any procedure a patient has to undergo that's additional to the primary procedure, I think has to factor in at some level. And I think if you have the choice of having the pacemaker or not having a pacemaker, I think most patients would opt not to have a pacemaker. So I think it factors in at some level, but ultimately it will be up to the clinicians to decide at what level.

Kevin Kotler - *Broadfin Capital - Analyst*

Kevin Kotler with BroadFin. I was just curious, the pacemaker rate in Medtronic's trial, they talked about like a 25% heading into their trial in terms of -- got pacemakers a week before. And I just don't know what the data was for partners, and if you could just comment on that.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Larry, do you know?

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

I want to say in PARTNER B, I think we -- I think ST had about a 5.5% pacemaker rate.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Going into the trial?

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Oh, going into the trial. Going into the trial, I think it was comparable. I think it was about a quarter of the patients had pacemakers. I'm remembering this more from our continued access data series. I think we had about -- I want to say we had about 2400 patients, and I think about 400 or 500 of them had previously had pacemakers. So I think the 20% to 25% is probably comparable.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Jason?

Jason Mills - *Canaccord Genuity - Analyst*

Jason Mills, Canaccord Genuity. What have you learned from this experience, Mike, with respect to Medtronic? They're going to be on the market earlier; the data looked better. You've got a lead in Japan. What can you take from this learning experience and apply it in Japan? What will you do differently, if anything, as you expand that market? That market, I think -- for those that are looking at the stock and looking at the numbers, I think honestly that's where people are thinking maybe you're going to get the most of your growth for the time being.

So how can you maximize that opportunity? And what can you do, if anything, to set yourself up better? Medtronic's coming; we know that -- to set yourself up better in Japan when they do.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

I'm not sure, is the short answer. When we went into the US, and as we go into Japan, no surprises. We're the first in; we're the innovator. And we say to ourselves, we need to behave in such a way that we treat with great respect the fact that we're the first. Sometimes things go a little slower in the beginning while people are learning, and you have to break that ice. And that goes along with being first. Being second is a little easier because there are many more knowns. And that is what it is. But we get a chance to build relationships with customers that are very close.

And we think we treat people in such a way that they'd like to be able to -- they'd like to stay with us. And so we put a premium on that. The experience in Japan we think will be a very good one. We think that will be a great market, but it will be deliberate in terms of what that the adoption rate is. I think the Japanese clinicians are largely very thoughtful and very conservative in terms of the way they adopt. But once they move, I think they move in a very deliberate fashion.

I think it's going to be extraordinarily popular. So, it's going to put a path, Jason. We're going to put the same burden on ourselves to make sure that we're behaving in such a way that we are the kind of people that they want to stay with when they have other choices.

Jason Mills - *Canaccord Genuity - Analyst*

I'd follow up just on the clinical side. I guess I'm a little bit surprised that -- and having access to you guys is great. But a little bit surprised that you're not lining up some guys that really know SAPIEN, and have used it -- you have John Webb -- those folks that you've had at your conferences, to talk about if not picking apart some of the CoreValve data, which I'm sure your sales guys will do in the marketplace, to talk about what's good about SAPIEN and where, competitively, you think you win. I guess the question is, why not? And is there anything to pick at, from your perspective, the data?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Well, thanks. Maybe it's a mistake on our part, but we're under the assumption that most of the people in this room are actually not going to implant many valves next year. And that the more important group that's out there are the clinicians. And so we're really going to focus our effort on trying to make sure that the folks that are really making decisions on what valves they are going to buy, they are the ones that will hear from us.

Certainly we have obligations to our investors, and we care deeply about how well informed they are. But these are going to be clinical decisions that are ultimately made over time, since you don't have any [proof].

Yes, Bruce?

Bruce Nudell - *Credit Suisse - Analyst*

Bruce Nudell from Credit Suisse. There are two findings that I saw when Patrick Serruys spilled the beans from the podium about the TVT registry details. One thing was only 25% of the patients were inoperable, which implied to me that recruitment in the unreferred who, presumably, are more inoperable or have high content -- are just difficult to get at.

And, secondly, that the STS score was 7, which is below the 8% cutoff in PARTNER IIa. Could you just explained that, with that latter finding in the context of -- is there indication creep? Are there explicable bases for truly on-label use with an STS of 7? And also, any commentary on inoperable.

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Yes. I think one of the things that I think is a little bit of a misnomer is when people -- when we talk about the incidence rate of aortic stenosis in this large untreated patient population, I think there's an assumption that people make, that -- that untreated population is largely non-operable. And I don't think that that's an accurate assumption. I think there's a lot of patients who could have surgery; they just opt not to have surgery. Maybe because they have elevated risk of advanced age. So I don't think the untreated population is all inoperable, by any stretch. I think there's the whole spectrum there.

So I think the fact that 25% of the patients -- or 20% to 25% of the patients in the TVT registry are inoperable, I think that's -- they collect that data, and so I think that that's pretty accurate. In terms of the STS score, there's a lot of things that aren't factored into the STS score. The biggest are porcelain aorta, which I think about 15% of the patients in our trial actually had a porcelain aorta. So those patients may have an STS score of as low as 1 or 2, but they're actually considered to be largely inoperable.

So that's one group. But the other huge one is frailty. Frailty doesn't show up anywhere in the STS risk score, and that's probably one of the biggest things that make surgeons uncomfortable not operating on patients is if they have advanced age and they're frail. And so those patients can have lower risk scores, but if there evaluated by two surgeons and they say, hey, I think this patient really is legitimately high-risk, then people are comfortable doing a TAVR on them. And, remember, every patient in the TVT registry had to be reviewed per the CMS guidelines -- or the NCD -- by two surgeons, and determined to be suitably high risk. So, I think there's very good controls, and I don't think we're seeing a lot of risk creep.

Bruce Nudell - *Credit Suisse - Analyst*

My follow-up for you is -- and I know we're not going to get much -- but given the market growth rate, given the emergence of competitors, given the fact that growth in the US is going to be challenging, and so you get indication expansion -- does this change your strategic posture? Does it change your -- the direction in which you want to take the Company?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

The short answer is no, Bruce. This was inevitable. There was going to be competition that came to the US, just like there was going to be competition across the globe. So it's coming a little sooner. Whether it was coming six months sooner or one year sooner, it is what it is. But does that change the fundamental direction of the Company? No, not in any way. We like the spaces that we compete in. We believe there's big, untreated groups of patients. We think that transcatheter heart valves is a growth opportunity for a long time.

There's going to be more than a decade of growth we think that goes along with this, as we continue to open up more and more patient groups. And the things we're encouraged by is that the technology is looking so good. Then we like our lineup of products. We're not afraid of competing in the marketplace. You can look to Europe to say, how are things going? And we've got a lineup of new products. We're super excited about SAPIEN 3; we've got CENTERA behind it. And there will be more products behind that.

So we're okay with the competitive nature with things, and we're not concerned. Now, what it might do to the 2014 numbers? Good question. We'll be conservative about that, and thoughtful, but not going to change the overall direction of the get company.

Kristen?

Kristen Stewart - *Deutsche Bank - Analyst*

Kristen Stewart from Deutsche Bank. Just as a follow up on that, so if you look out to -- I guess if you look at the market today, what would you say is the penetration rates within, call it, the high surgical risk? And just thinking forward without an expanded indication, do you think that there is still an opportunity for growth that Medtronic can enter the market next year, and you guys can still see some level of US sales growth?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Sure. I don't want to get in front of us in terms of what we're going to talk about at the investor conference. We'll try and lay this a little more thoughtfully. And obviously we got new input this week, so it will help us even sharpen our plans in terms of what might happen.

I don't know, Larry, do you have any comments?

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Clearly, I think one of the things we look at is Europe, and Europe continues to grow. We launched at the end of 2007 in Europe, and we continue to see good growth. One thing I'll just add on this, and I'm not intentionally trying to be defensive, although it might sound a little bit that way. For all the discussions we've had about the US launch, and maybe the adoption wasn't quite as fast as we would've hoped, and maybe the economics has been a lot more challenging, the one discussion that we haven't had is that the technology isn't delivering on the promise.

You're not hearing about people saying, we're having bad cases or the technology is not so good; or when you rolled it out to a lot of smaller centers they started getting really, really bad outcomes; it's not a trainable procedure. Those fundamentals are still as strong as they've ever been. And in fact, I think three years in, you look at our three-year data, and it's actually probably more impressive than our one-year data.

So I think the long-term fundamentals of these markets, and the benefits this technology provide for patients are probably stronger now than they've ever been.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Maybe just as the punctuation on the point you made was that the technology was introduced in Europe in 2007, and we just reported a quarter where here's growth rate is strong double-digit. Actually, probably, close to -- market growth was well over 10%, with Edwards growing more like 20% O-US.

Kristen Stewart - *Deutsche Bank - Analyst*

And just to push you a little bit, just on the US, you do have this situation where Medicare reimbursement, with particular guidelines on the number of centers, the criteria they have to have, and the patient characteristics, which really doesn't exist in Europe. So, you may have greater opportunities to grow in Europe just because of those factors, not because of your technology or anything like that. So, just help me understand why that isn't going to be a gating factor.

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Sure, sure. Boy, I don't know what you all think of the Medicare reimbursement, but it could be a lot worse. It's not bad. The fact that we get reimbursement for our centers at the same rate of payment as open-heart valve replacement, I think is pretty fair and pretty remarkable. And I think it provides enough incentive for this market to be able to grow dramatically. I don't think our reimbursement climate in Europe is better.

Possibly, Germany is a pretty positive one; but you get beyond that, I don't know that it's better than the US situation. So, no, I'm not discouraged. Do we think the NCD is constrictive? Do we think they are keeping it to too few centers? Yes, probably, on the margin, we think that it is too restrictive. But it is in the hands of the leaders. It is in the hands of the largest centers in the United States. And we think that they are able to do very well with the reimbursement that's in place, by and large. And it's a young procedure, and getting better all the time.

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Yes, I think that probably the most critical thing is the economics, as they exist today, are the worst that they are ever going to be. We rolled this out; we asked sites to focus on outcomes; but we have a lot of people in the room. Everybody is trying to make sure they do good cases and they adopt the training program. We're just now really scratching the surface on aggressive length of stay programs and making sure people are discharging without impacting the PAC, and those sorts of things.

But new technology is also going to make the procedure easier, as they do more percutaneous closure. Those economics are just going to continue to get better and better with time. I think it is a young procedure, and there's still a lot for people to learn.

Matt Taylor - *Barclays Capital - Analyst*

Matt Taylor with Barclays. A couple of questions on mitral valves. I wanted to see if you could comment at all on your animal data so far. And also how your designs differentiate them from some of the other designs that we've seen here at TCT. And then maybe, finally, if you do get first-in-human by the end of the year, how long do you think it would take you to commercialize that product?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Yes, thanks. I'm probably going to disappoint you with the answers. And we're really not going to end up getting into probably any of those subjects until we see you at the investor conference. So the thought is that we'd give an update on mitral programs at that time. You can imagine, this is for competitive reasons. We don't know if there's any reason that we'd have to be out necessarily promoting a specific design or commenting specifically on our path to first-in-man, or exactly how that goes.

It's novel when you go into first-in-man. Doing the humans are different than anything that we're able to replicate before we have a first-in-man experience. So we think it's just best to save our comments until we have some experience.

David Erickson - *Edwards Lifesciences Corporation - VP of IR*

One more question. Danielle, in the back. Can we get her a mic?

Danielle Antalffy - *Leerink Swann - Analyst*

Thanks, guys. Good morning. Danielle Antalffy from Leerink Swann. Just to follow up on the pacer comment that Raj made earlier -- understanding that it's a clinician decision, but ultimately there's also some economics that are involved here. How is the pay center reimbursed today with the TAVR procedure? And could that potentially change, once we have a TAVR on the market that has a 22% pacer rate?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Yes, I think, by and large -- maybe Larry knows some specifics, and feel free to add to this -- but the payment on the TAVR is a DRG. So there's a single payment that goes to the hospital based on the risk of the patients and the procedure itself. The fact that there was a pacer added, I don't know that really changes that reimbursement at all.

Larry, do you know if there's a specific reimbursement? It may be peculiar to when the pacer goes in. Maybe that's a separate, billable event.

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Mike's right. The DRG gets paid for the entire procedure, and if the patient requires a pacemaker, that gets covered under that same DRG. There's not a separate DRG if a pacer goes in during that procedure.

Danielle Antalffy - *Leerink Swann - Analyst*

So there's no add-on payment or anything like that here in the US?

Larry Wood - *Edwards Lifesciences Corporation - Corporate VP, Transcatheter Heart Valves*

Our understanding is there's no add-on payment, no.

Danielle Antalffy - *Leerink Swann - Analyst*

Okay. And then just to follow up, I know you're not trying to sell us a valve. But it would be great if you guys could give us some sense of what your marketing message will be once CoreValve hits the market. What will you be focused on as you are out there selling against CoreValve?

Mike Mussallem - *Edwards Lifesciences Corporation - Chairman and CEO*

Sure. Well, there shouldn't be any surprise. We've competed against CoreValve for many, many years in Europe. And so you can see pretty much what the score is there, and what our messages are. And we're very pleased. We continue to bring a lot of data, and we let the data speak for itself. And we are proud of our data, and we're proud of the way it performs. And we like the way we stack up versus CoreValve and the rest of the competitors.

And we're just going to keep pushing the state-of-the-art. We're on offense here, pushing as hard as we can to continue to bring better and better technology, and to just supplement clinicians with their own patient selection and training, et cetera. And we're going to continue down that path.

Anyway, thanks very much for all your interest. We'll hang around here and have a little bit more breakfast until 8 o'clock. I know there's sessions that many people are interested in getting to. We really appreciate your interest in Edwards.

EXHIBIT D

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

EW - Q3 2013 Edwards Lifesciences Earnings Conference Call

EVENT DATE/TIME: OCTOBER 28, 2013 / 2:00PM GMT

OVERVIEW:

Edwards Lifesciences announced 3Q13 sales of $496m and EPS of $0.68. Management gave sales guidance of $520-550m for 4Q13 and $2.0-2.1b for 2013, as well as guidance for EPS excluding special items of $0.81-0.85 in 4Q13 and $3.00-3.10 in 2013.

THOMSON REUTERS

CORPORATE PARTICIPANTS

David Erickson *Edwards Lifesciences Corp - VP, IR*

Mike Mussallem *Edwards Lifesciences Corp - Chairman and CEO*

Tom Abate *Edwards Lifesciences Corp - CFO*

CONFERENCE CALL PARTICIPANTS

Larry Biegelsen *Wells Fargo Securities, LLC - Analyst*

Amit Bhalla *Citigroup - Analyst*

Jason Mills *Canaccord Genuity - Analyst*

Michael Weinstein *JPMorgan Chase & Co. - Analyst*

David Roman *Goldman Sachs - Analyst*

Misha Dinerman *Piper Jaffray & Co. - Analyst*

Bruce Nudell *Credit Suisse - Analyst*

Danielle Antalffy *Leerink Swann & Company - Analyst*

David Lewis *Morgan Stanley - Analyst*

Kristen Stewart *Deutsche Bank - Analyst*

Glenn Novarro *RBC Capital Markets - Analyst*

Bob Hopkins *BofA Merrill Lynch - Analyst*

Matt Taylor *Barclays Capital - Analyst*

Suraj Kalia *Northland Securities - Analyst*

Rick Wise *Stifel Nicolaus & Company - Analyst*

PRESENTATION

Operator

Greetings, and welcome to the Edwards Lifesciences Corporation third-quarter 2013 earnings conference call.

(Operator Instructions)

As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, David Erickson, Vice President, Investor Relations. Thank you, Mr. Erickson, you may begin.

David Erickson - *Edwards Lifesciences Corp - VP, IR*

Welcome, and thank you for joining us today.

Earlier this morning, we issued a press release with our third-quarter 2013 financial results. On today's call, we will discuss those results and follow our prepared remarks -- following our prepared remarks, we will open up for questions. Our presenters today are Mike Mussallem, Chairman and CEO, and Tom Abate, CFO.

Before I turn the call over to Mike, I would like to remind you that during today's call we will be making forward-looking statements that are based on estimates, assumptions and projections. These statements include but aren't limited to, our expectations regarding sales and sales growth, gross profit margin, earnings per share, SG&A, R&D, taxes, free cash flow, diluted shares outstanding, interest expense and foreign currency impacts.

These statements also include our current expectations for the timing, status, and expected outcomes of our clinical milestones and trials, regulatory approvals, regulatory compliance and reimbursement, as well as expectations regarding market growth and opportunities in the US and Japan, launches of safety and products and associated economics, new product introductions, impact of competition, and the timing and impact of the patent litigation. These statements speak as only as of the date on which they are made, and we do not undertake any obligation to update them after today. Although we believe them to be reasonable, these statements involve risks and uncertainties that could cause actual results or experiences to differ materially from the forward-looking statements.

Information concerning factors that could cause the differences may be found on our press release, our annual report on Form 10-K for the year ended December 31, 2012, and our other SEC filings which are available on our website at edwards.com. Also as a quick reminder that when we use the terms underlying, excluding the impact of foreign exchange and excluding special items, we are referring to non-GAAP financial measures. Otherwise, we are referring to our GAAP results. Additional information about our use of non-GAAP measures is included in today's press release.

Now I will turn the call over to Mike Mussallem. Mike?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Thank you, David.

This quarter we are pleased to report strong sales growth driven by transcatheter and surgical heart valves, as well as well as solid bottom-line results. A number of important transcatheter valve developments were among this quarter's highlights, including the approval to begin the US clinical study of our most advanced valve, SAPIEN 3, expanded approval to include alternate delivery approaches for SAPIEN in the US, a favorable patent infringement ruling in Germany, and the receipt of reimbursement in Japan. This approval means Edwards is the first to offer this novel technology to patients in Japan, which brings our life-saving therapy to over 60 countries.

Now turning to the quarterly results, reported sales grew 11% to $496 million. Sales growth, excluding the impact of foreign exchange was 13%, driven by transcatheter and surgical heart valves with a strong contribution from Europe. In transcatheter heart valves, third-quarter sales grew 39% to $172 million, driven by the ongoing US SAPIEN launch and strong growth in Europe. In the US, THV sales for the quarter grew 56% to $86 million, which included $12 million of clinical sales, but was reduced by $2 million of net stocking.

As we previously projected, activities slowed sequentially due to seasonality, and the impact of consignment conversions exceeded stocking sales. Clinical sales were driven by enrollment in our PARTNER 2a trial and the ongoing nested registries. We estimate commercial procedures grew 80% over last year. As a reminder, in third-quarter last year, net stocking had a favorable $8 million impact to sales.

At the end of September, 265 sites in the US offered SAPIEN to their patients. Overall, we continue to believe that TAVR economics and hospital capacity are not yet optimized at most sites, and there remains significant opportunity for improvement. Our US team is strengthening its capability to educate sites on TAVR economics, and share best-demonstrated practices from some of the leading US programs. Importantly, nearly 15,000 patients in the US have been treated with our transcatheter heart valves over the past two years, and clinicians continue to maintain very high procedural success rates. In September, the FDA approved the revised labeling for our SAPIEN valve to include alternate access points, in addition to the transfemoral and transapical approaches. This change enables US reimbursement for patients, regardless of which implantation approach a physician uses.

Outside the US, THV sales grew 25% over last year, or 20% excluding the impact of foreign exchange. Growth was driven primarily by transfemoral units. We estimate the favorable patent infringement ruling in Germany had negligible impact on sales in the quarter, as affected customers continued to work down inventory of the competitor's product. While more recent competitors had a small impact on this quarter's results, we expect it to be greater in the fourth quarter due to new product approvals.

Now updating our clinical and product development milestones. We are actively working with FDA, and continue to expect a mid-2014 US approval for SAPIEN XT with the NovaFlex delivery system, and anticipate a rapid introduction will follow. We are proud to announce that we have completed enrollment in cohort A, the surgical arm of the PARTNER II trial. This is the first randomized study -- the first randomized trial to study transcatheter heart valves in moderate risk patients, which has the potential to significantly expand patient access to transcatheter valve technology.

In August, we received FDA approval to expand our PARTNER II clinical trial to include a 500 patient cohort to study one-year outcomes of our SAPIEN 3 system in high risk and inoperable patients. Recently we started enrollment, and are excited to bring our most advanced valve delivered through a 14 French inch eSheath, and designed to reduce paravalvular leak to patients in US.

In Europe, we remain on track to receive a CE Mark to launch our SAPIEN 3 valve by year-end. We completed an initial clinical experience with our CENTERA valve, and expect to begin another clinical series with an enhanced delivery system in the next several months. During the quarter, we received reimbursement for SAPIEN XT in Japan, which became effective October 1. We have completed our first commercial cases, and since sites are required to undergo a rigorous certification process, we anticipate sales will ramp slowly. We believe transcatheter valve technology will be particularly attractive to Japanese patients, and the introduction of our SAPIEN XT valve in that market should contribute meaningfully to sales beginning next year.

And finally, we received approval in the quarter for SAPIEN in Australia and SAPIEN XT in Canada. Treating mitral disease with transcatheter technology continues to be one of our primary development efforts, and we still believe a first-in human experience with a transcatheter mitral valve is likely in 2013. We expect to provide an update at our December investor conference. We are continuing to invest broadly in structural heart disease solutions, and have dedicated teams working on multiple therapies.

In our patent litigation with Medtronic, we had two significant recent developments. First in Germany, the Court found that Medtronic infringes our Spenser patent. The validity of this patent is still being contested. We posted the necessary bond, putting into effect the Court's injunction and recall. Contrary to our interpretation of the Court's decision, Medtronic has not instructed hospitals to return product. We have requested further enforcement action by the Court, and we anticipate more clarity in the next few weeks. Second, in our US case involving the Andersen patent, the US Supreme Court has denied Medtronic's request for a further review of the case. Edward's request for a permanent injunction and additional damages are pending before the Delaware trial court, and no timing for these decisions has been established.

In summary, we continue to expect global transcatheter heart valve underlying sales growth of 25% to 30%, and are tightening our 2013 sales guidance range to $700 million to $730 million. Included in our assumptions are US sales at the low end of our previous guidance range of $350 million to $400 million, and stronger OUS performance. In the fourth quarter, we expect minimal impact from the German injunction and the Japan launch.

Now turning to surgical heart valve therapy group, reported sales increased 3% over last year to $192 million. Excluding the impact of foreign exchange, sales grew 6% compared to the prior year driven by unit growth. This quarter's growth was led primarily by strong performance in the US and Europe, and tempered somewhat by a competitor's launch in Japan. INTUITY contributed approximately 2% to total sales growth.

Globally, our pricing remains steady. ASPs were stable in the US and higher in Europe due to INTUITY, but offset by geographic mix. In the US, sales grew 6 7%. We estimate that we regained share in the quarter, and that the market grew in low single digits. We also believe we are beginning to benefit from our recently published long-term durability data.

In Europe, we are making good progress on our key INTUITY milestones. We continue to expect a CE Mark in the near future for INTUITY Elite, our next-generation platform which has been well-received by clinicians for its lower profile. In the US, enrollment in our TRANSFORM trial remains on track, and we now have upgraded all sites to INTUITY Elite. Also in the US, we continue to enroll patients in our COMMENCE IDE trial studying the GLX tissue on our aortic and mitral Magna Ease platforms. Based on current trends, we are raising the bottom end of our sales growth range in surgical heart valve therapy, and now project 3% to 5% underlying growth in 2013.

Turning to the Critical Care product group, total sales of $132 million for the quarter declined 5% over last year. The primary driver of the decline was the foreign exchange impact in Japan. Excluding the impact of foreign exchange, sales increased 1% as double-digit growth of FloTrac was

nearly offset by the continued reduction of distributor inventories in China, and the ongoing exit of our ACCESS product line. The incorporation of our noninvasive monitoring technology into our EV1000 platform is continuing, and the integrated product remains on track to be introduced in 2014. This quarter, noninvasive products once again contributed modestly to sales.

We remain enthusiastic about the significant opportunity represented by our GlucoClear system, and are encouraged by the progress on our 2013 goals. We completed enrollment in our ICU accuracy study in Europe, and expect it to demonstrate compelling results in the hospital setting. We expect to receive further insight on the pathway toward US approval in the fourth quarter. Based on our year-to-date results, we now expect full-year 2013 underlying sales growth for Critical Care product group to be at the bottom of our previously stated 2% to 4% range.

And now, I will turn the call over to Tom.

Tom Abate - *Edwards Lifesciences Corp - CFO*

Thanks, Mike.

Turning to the financials, this quarter our strong sales performance in valves allowed us to achieve diluted EPS of $0.68, representing growth of 17% over the prior year. At the same time, we increased our R&D investments by 14%. During the quarter, we repurchased 3.1 million shares for $250 million, and now project fully diluted shares outstanding to be between 111 million and 112 million at year-end. Just after the end of the quarter, we issued $600 million of five-year notes at 2 7/8%, and fully paid down the $532 million balance on our revolving credit facility.

For the quarter, our gross profit margin was 73.8%, compared to 75.1% in the same period last year. The reduction was driven by higher manufacturing costs, as we prepare for the SAPIEN XT launch in the US and SAPIEN 3 launch in Europe, as well as the reduced benefit from foreign exchange of 40 basis points. These items were partially offset by a more profitable product mix of 180 basis points.

Excluding special items for the fourth quarter of 2013, we expect our gross profit margin to remain at approximately 74%. Third-quarter SG&A expenses were 36.4% of sales, or $180 million, an increase of 8% over the prior year. This increase was driven primarily by US and Japan transcatheter valve launch-related expenses and US Medical Device tax, partially offset by lower incentive compensation and FX. As a percentage of sales, SG&A should decrease in the fourth quarter, and we continue to expect SG&A to be between 36% and 37% of sales for the full year.

We continue to aggressively invest in R&D, and spending in the quarter grew 14% to $84 million or 17% of sales. This increase was primarily the result of additional investments in multiple heart valve clinical studies. For the full year, we continue to expect R&D to be approximately 16% of sales.

Net interest expense for the quarter was $1 million. In the fourth quarter, we expect net interest expense will increase to approximately $4 million to $5 million as a result of the $600 million debt issue issuance earlier this month. We estimate our recent share repurchases will largely offset the EPS impact of the higher interest expense, and therefore, have a neutral effect on our fourth-quarter EPS. Our reported tax rate for the quarter was 23%, down from 25.9% in the prior year, due primarily to the absence of the federal R&D tax credit last year, and favorable reserve adjustments this year. We continue to expect our full-year tax rate excluding special items to be at the low end of our 23% to 24% range.

FX rates negatively impacted third-quarter sales by $9 million compared to the prior year, driven by the weakening of the yen. Compared to our recent guidance, FX rates negatively impacted EPS by $0.01. At current FX rates, we now expect a $45 million negative impact to full-year 2013 sales. Free cash flow generated during the quarter was $110 million. We define this as cash flow from operating activities of $147 million, less capital spending of $37 million. For 2013, excluding special items, we continue to expect free cash flow to be between $270 million and $310 million.

Turning to our balance sheet, at the end of the quarter we had cash, cash equivalents and short-term investments of $758 million. Total debt increased to $532 million, as a result of our share repurchases during the quarter. Our DSO at the end of the quarter was 58 days, and our inventory turns were 1.7, both consistent with the prior quarter.

Turning to our sales and earnings guidance, at current exchange rates for the surgical heart valve therapy product group, we are raising the bottom end of our range and now expect sales of $780 million to $810 million. In transcatheter heart valves, we have tightened the range to $700 million to $730 million, which reflects US sales at the low end of our $350 million to $400 million range, and stronger OUS performance. In the Critical Care product group, we now expect sales at the low end of our previous $530 million to $570 million range.

In summary, we are reiterating our full-year guidance with sales of $2 billion to $2.1 billion, and earnings per diluted share excluding special items of $3 to $3.10. For the quarter -- for the fourth quarter of 2013, we project total sales of $520 million to $550 million, and diluted EPS, excluding special items, to be between $0.81 and $0.85.

And with that, I will hand it back to Mike.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Thanks, Tom.

We continue to project double-digit underlying sales growth in 2013, and believe that our many clinical and commercial accomplishments this year have strengthened our leadership. This positions us well for continued success, and we remain committed to developing innovative technologies in structural heart disease and critical care that provide clinicians with transformational therapies to treat their patients.

Before we open up for the questions, I would like to remind you about our 2013 investor conference on Monday, December 9, in New York where we will provide an update on our new technologies, as well as outlook for 2014.

And with that, I will turn it back over to David.

David Erickson - *Edwards Lifesciences Corp - VP, IR*

Thank you, Mike.

If you haven't yet RSVP'd for our December investor conference, you can do so on our website. And as a reminder, to those of you who are here in San Francisco for the TCT conference this week, Edwards is hosting an informal breakfast meeting on Thursday morning at the Intercontinental Hotel. Please RSVP for the breakfast by contacting a member of our Investor Relations team.

As we move into Q&A, I would ask that you please limit the number of questions you ask, so that we can allow broad participation. If you have additional questions, please reenter the queue, and we will try to get to as many people as we can during the rest of our time.

Operator, we are ready for questions, please.

QUESTIONS AND ANSWERS

Operator

Thank you.

(Operator Instructions)

Larry Biegelsen, Wells Fargo.

Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

Good morning. Thanks for taking the question. Mike, maybe if we could spend a minute on the Q4 guidance, and how you are thinking about that. If I am doing the math correctly, I think this quarter, TAVI sales were up 39%. The midpoint of the guidance for Q4 implies about 19%, 20%. The US in particular, implies a pretty significant deceleration in growth from what you reported this quarter. So maybe you can talk a little bit about that? And I know there was a lot of stocking in Q4 2012. So maybe if you could talk about just the commercial growth that is implied in kind of the US guidance? Thanks.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. Thanks, Larry. Yes, the -- we actually expect a good quarter in the fourth quarter, and I think there is enough guidance out there, with three quarters under our belt, and you now have our full-year expectation you have a pretty good feel of what we think is going to happen. But, yes, if you are just looking at growth rates on a reported basis, you have to take into account what you mentioned, which is the fact that we had positive net stocking in the fourth quarter of last year that was pretty substantial.

Remember, that was the quarter when the Cohort A was approved and transapical came into being. And so, that was a boost to the quarter's -- much in stocking. As you see this quarter actually, we had negative net stocking. And we wouldn't be surprised if it would stay -- it is certainly not going to be the positive driver that it was in the fourth quarter of last year.

Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

Thanks. And then just one on mitrol. Obviously, encouraging commentary from you earlier, that you still think the first-in-man is likely this year, only two months left in the year. Is there any additional color you can give us, Mike, on what gives you the confidence that you will be able to do a first-in-man in 2013? And I will drop. Thanks.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes, thanks, Larry. As you can imagine, it is quite a process for us to move forward with a first-in-man experience. And I think the good news that you should take away from our continued statement that it is likely this year, is that we continue to make progress, and to achieve milestones along that way. And we really don't have much more to share. Just wanted to let you know that we are going to provide an update at the investor conference in December. And so, I would say, really stay tuned for that.

Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

Thank you very much.

Operator

Amit Bhalla, Citi.

Amit Bhalla - *Citigroup - Analyst*

Thanks. Mike, just on fourth quarter and Germany, can you talk just a little bit about the impact there? You said you are not expecting much from Germany, and you expect Medtronic to remove its products. How does that balance against the compassionate use that is still allowed, and why is there not just greater contribution into the fourth quarter guidance from Germany?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. It is a good point. So just to keep in mind, what is going on there, recall that in anticipation of the injunction, that Medtronic provided some excess sales it appears to their accounts. And I think that they acknowledge that. And so there is some inventory that still remains, and we believe that that was being worked off to some extent in the third-quarter. There is a difference of opinion on the Court's interpretation. We feel that the Court expected customers to return product.

Medtronic has not asked their customers to do that. And so, we have gone back to the Court to provide clarity in that regard. And further, as you know we proactively provided for compassionate cases, and have a specific set of valves that we thought were appropriate -- that wouldn't be appropriately treated with an Edwards system. I think Medtronic may have a different interpretation, a broader interpretation of that. We are also asking the court for clarity on that point.

Amit Bhalla - *Citigroup - Analyst*

And Mike, just a second question, just on US demand. Yesterday at the conference, there was a discussion of a TVT registry, in which the speaker said, that US market plateauing at about 250 sites and 800 US procedures per month. Do you have a comment on the US market saturating or plateauing?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

No. We don't believe that the US market is plateauing. I think the TVT registry has a substantial look back there, and I am not sure that you are able to really draw conclusions from the collection of that data. No, our experience is that there is still a growing market in the US. And I think that -- the results this quarter that we believe that procedures versus third-quarter a year ago grew approximately 80%, is a pretty good indication that this is not a flat market.

Amit Bhalla - *Citigroup - Analyst*

Thanks, Mike.

Operator

Jason Mills, Canaccord Genuity.

Jason Mills - *Canaccord Genuity - Analyst*

Hi Mike, thanks for taking the question. Can you hear me okay?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Hear you great, Jason.

Jason Mills - *Canaccord Genuity - Analyst*

Great. With so much scrutiny on just one aspect of one division in your business, US TAVI, wondered if you could comment about the US business commercial, and also including clinical. But if -- and correct me if I am wrong, but last year I think you had somewhere in the mid-single digits from

a clinical perspective in terms of contribution to US TAVI. And this year, it was significantly bigger than that. In our research, some of your bigger clinical centers, in some cases preferred to enroll patients than to implant with the -- in commercial setting, given the different innovations, the different products that they have access to.

So how would you have us look at your US business? I know you gave commercial sales growth, but should we include clinical in that, given the phenomenon of clinical centers perhaps in some cases preferring to enroll than to implant in commercial?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes, thanks, Jason. As you pointed out, there were significant clinical sales this quarter, larger than they have been in the past, particularly because there was pretty stout enrollment of the PARTNER II trial with SAPIEN XT. And if you just step back, I think a reasonable way to think about this is, those cases that are being done clinically could very well have been done commercially. And I like to look at the total number of procedures that are happening, and think that clinical volume should be sort of added to the commercial volume, when you consider what is the demand that is in the marketplace. So I think that is a correct observation.

We expect the clinical demand to stay pretty robust here in the future. And you have to remember, that there is also competitive critical demand as well. So I think that is worth taking into account, when you think about just how big the market is or how fast it is growing.

Jason Mills - *Canaccord Genuity - Analyst*

That is helpful. And so for my follow-up, let's stay with US TAVI. I know you are not ready at this point to give your 2014 expectations. But perhaps you could give us a sense for how you are building that up, and what variables you see as the biggest drivers to growth in your US business next year, in terms of how you are building up the number of synergy think will contribute to that number? And then utilization rates, just juxtaposed to your experience in Europe in year three there, versus what you may expect here in terms of utilization, and how that might trend next year? Thanks, Mike.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Sure. Well, I think one of the things that we indicated is over time the impact of stocking and consignment will diminish. And so, we think that will be a less pronounced effect in 2014 than it is in 2013. You are right, we are not going to give specific guidance about 2014. But the high procedural success rate gives us confidence that we have got a very robust and growing procedure base, and that will continue. And there -- one of the biggest headwinds I think to growth so far, has been some of the economic concerns, and those just continue to improve over time. We still have a young procedure and that is we believe getting considerably better on a consistent basis. And so, we think that is really what will provide the underlying lift for continued growth next year.

And as you point out, in Europe, here we are, this is the sixth year after introduction, and Europe just had a growth quarter of about 20%. So pretty remarkable. I know it is -- maybe the comparison last year was at the depth of some problems in Europe, but nonetheless, it is pretty encouraging to see how that is going.

Jason Mills - *Canaccord Genuity - Analyst*

Thanks.

Operator

Mike Weinstein, JPMorgan.

Michael Weinstein - *JPMorgan Chase & Co. - Analyst*

Thanks for taking the questions. Just two quick clarifications first. One, I wasn't sure what the fourth quarter full-year US TAVI guidance is now, if that had changed? And second, Mike, will we not hear anything on the mitral side until the Analyst meeting? If you could clarify that? Thanks.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. So yes, on the mitrol question, I don't think you should anticipate that you are going to hear things from us until the investor conference. We don't have any plans to report anything at this point. And then in particular, you are asking about what the guidance is for the remainder of the year? (Multiple Speakers).

Michael Weinstein - *JPMorgan Chase & Co. - Analyst*

I know you had the $350 million to $400 million range, but did you change that today?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

We, what we have said is that you should expect it to be at the low end of that range.

Tom Abate - *Edwards Lifesciences Corp - CFO*

Correct.

Michael Weinstein - *JPMorgan Chase & Co. - Analyst*

Okay. And then --

Tom Abate - *Edwards Lifesciences Corp - CFO*

We kept the overall global range the same, because of the stronger OUS performance.

Michael Weinstein - *JPMorgan Chase & Co. - Analyst*

Got you. And then just one question -- I don't know if you caught the [Tweak's] comments yesterday on the TVT registry. I felt like you let a little something slip out of bag, ahead of the publication. But he said that 25% of the implants to date -- and this is in the first 50 to 700 cases -- had [FTS] scores below 5. Is that possible? I -- it just didn't seem right to me, but I was hoping you would know the data better than we would.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. I don't know about that, Mike. We understand that they are struggling to enroll that trial. And I think it is probably a result that there is a -- (Multiple Speakers).

Michael Weinstein - *JPMorgan Chase & Co. - Analyst*

No, no, I am not talking about [Sertavi], Mike, I am not talking about sertavi, I am talking TVT -- (Multiple Speakers)

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Oh, the registry, oh the TVT?

Michael Weinstein - *JPMorgan Chase & Co. - Analyst*

Yes.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Are you talking about the US or European data?

Michael Weinstein - *JPMorgan Chase & Co. - Analyst*

No. No, the US TVT registry.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. that is doesn't sound likely to us. We are not sure that SDS captures all the factors. Sometimes what confounds that is the frailty or porcelain aorta. So maybe that is confounding the statistics, but broadly we think people are pretty disciplined about the way that they utilize the valves.

Michael Weinstein - *JPMorgan Chase & Co. - Analyst*

That is what I was wondering. Okay. Perfect. Thank you.

Operator

David Roman, Goldman Sachs.

David Roman - *Goldman Sachs - Analyst*

Thank you, and good morning. I wanted to come back to the surgical valve business which you kind of glossed over a little bit in your prepared remarks, though you did see somewhat of a turn in that business. So I am hoping you could walk us through in a little bit more detail, what is happening with that franchise? To what extent if any are the centers seeing a pull-through effect from having TAVI programs in the US? And then how should we think about the surgical valve business going forward from a cannibalization standpoint?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes, thanks very much. The -- we are -- we still believe that there will be a halo, although we just haven't seen substantial impact in our results so far. The growth this quarter was unit growth. And so, we believe that the market was probably growing in low single-digits, and that we also had share increase I think, as we are regaining share in the US is part of that. We saw growth both in THV accounts and non-THV accounts this quarter. So both sort of lifted. So we are pretty optimistic about our surgical heart valves franchise in terms of where it is right now. Does that answer your question?

David Roman - *Goldman Sachs - Analyst*

Yes. (Inaudible) And then I guess the corollary question to that would be, if you are not seeing much of a halo effect or pull-through effect, why wouldn't this business see increased pressure over time as this PARTNER A group starts to pick up as a percentage of total units?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. It is a good question, and we will get deeper into that at the investor conference. But big picture is, yes, there will be some pressure, and some cannibalization, of course. But we think that the awareness of aortic stenosis is going to increase. It is a largely untreated population, and that there are likely to be more people that flow into system, and so we will get a boost from that. And so, we are not sure that it is just purely a subtractive effect.

David Roman - *Goldman Sachs - Analyst*

Okay. Got it. And maybe just for Tom on the P&L. Just a clarification around the moving parts in the gross margin line, can you maybe first give us some perspective, what was the underlying or sort of real gross margin this quarter? And then how long do we see this headwind from inventory build?

Tom Abate - *Edwards Lifesciences Corp - CFO*

Yes, that is a good question. I think we are going to see the inventory effects throughout the launch, is going to continue into 2014. When exactly? I don't have a date, but it is a number of things that are involved with the training and inventory and so forth. So I think that is likely to continue into the future. I would say this -- the benefit, we are still seeing some benefit in this quarter from FX, if you just isolate the current quarter. But that is pretty much gone by next quarter.

So we had a strong first half. Remember, we were getting helped 150 to 100 basis points. We also had a real strong benefit last year, second half. So but that is tapering down. Now, of course, as you wrap around rates whenever you have a big movement, that is pretty normal until the next movement. So predicting FX, we will take another shot at it in December, but it is always a variable.

David Roman - *Goldman Sachs - Analyst*

Okay. Thank you.

Tom Abate - *Edwards Lifesciences Corp - CFO*

You bet.

Operator

Brooks West, Piper Jaffray.

Misha Dinerman - *Piper Jaffray & Co. - Analyst*

Yes, hi. This is actually Misha Dinerman in for Brooke. I was just wondering, Mike, if you could give us an update on TA training, and how the rollout there is going? How many of the sites have been now set up with training? And -- (Multiple Speakers) -- go ahead.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. Thanks. I think at this point, a great, great majority -- I don't know the exact number, but my estimate would be it would be 95% or more of sites in the US are trained on transapical approach.

Misha Dinerman - *Piper Jaffray & Co. - Analyst*

Okay. Great. Thank you.

Operator

Bruce Nudell, Credit Suisse.

Bruce Nudell - *Credit Suisse - Analyst*

Good morning, thank you. Mike, one of the consternations about the stock is the view that the US market, given the constraints of the NCD can't really grow that fast, until there is indication expansion. And that given the emergence of competitors and just trialing efforts that are going on in clinicals, that it is going to be difficult for Edwards to grow the US TAVI business reliably in 2014 and 2015? And just kind of schematically, how do you respond to that? And is there any -- anything we should be thinking about that we are maybe missing?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. We continue to be optimistic about the US market. I think the improving economics will be gradual, but I think they will be deliberate, and we will see that. And we think as economics improve, that it will stimulate hospitals to increase their capacity, and to further develop their referral networks. So that is just a -- it would be an underlying boost.

Remember, we expect a SAPIEN XT approval next year, which we think is also very helpful. And that comes along with additional sizes, so we think that is also helps increase the number of patients that you might touch in the United States, compared to just the SAPIEN technology that is there today.

Bruce Nudell - *Credit Suisse - Analyst*

And Mike, my follow-up is about the kind of hospital profitability situation. And just to put a clarifying point on it, if a patient is mapped to the correct MS-DRG, and you can reduce length of stay with kind of discharge to home, that in your mind really will allow the hospital to kind of pocket more of the profit, and there won't be some recoupment on the part of CMS?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. I think that is right. Overall, we believe that profitability is not only improving, we think that most hospitals today are profitable on a per procedure basis. And as they improve their economics, for example, improve their length of stay and have proper discharge planning, yes, the benefit comes to the hospitals.

Bruce Nudell - *Credit Suisse - Analyst*

Thanks so much.

Operator

Danielle Antalffy, Leerink Swann.

Danielle Antalffy - *Leerink Swann & Company - Analyst*

Hello?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Hi, Danielle.

Danielle Antalffy - *Leerink Swann & Company - Analyst*

Hi, sorry about that. Thanks so much for taking the question. Mike, I was hoping I could follow-up on the mitrol program. Sorry to harp on this, but can you give us any color on sort of what are the milestones that still need to be hit, before we can go first-in-man? And then secondly to follow-up on that, how quickly can this go from first-in-man into a pivotal CE Mark trial? Thanks.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes, we really haven't gone to the point where we lay out the specific milestones. I think as we have mentioned, we go through quite a process -- all of our in vitro tests, as well as the early preclinical tests that we would do, both on acute animals and chronic animals. So it is quite a process, and I don't know that it is appropriate to get into that in a deliberate way.

We think there is a lot to learn in a first-in-man. There are no great models for really doing this in the mitrol position. And so, I think getting in front of ourselves would be inappropriate. We are going to try and bring this more to life, when we are with you at the investor conference. And so we will try and get much deeper, but I think at this point, it -- we will hesitate to make any projections beyond that. We think it is likely that we are going to get into the first-in-man, and we look forward to that experience.

Danielle Antalffy - *Leerink Swann & Company - Analyst*

Okay. Great. Thanks. And I was hoping you could comment on your Q4 guidance and for OUS THV sales, and how you are factoring in -- just this earlier this morning, a competitor got a next-gen valve CE Mark approval. So how you are thinking about the competitive ramping up in Q4, particularly since you don't expect to benefit from Medtronic in Germany quite yet? Thanks.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes, thanks. We have been really pleased with both what the market has been doing in Europe, and also our performance compared to competitors. And that has gone very well, and we felt like we leave the third-quarter with a lot of momentum. I think what was just approved this morning is no surprise to us. This is fully what we expected, and that is fully anticipated, and in our guidance.

Danielle Antalffy - *Leerink Swann & Company - Analyst*

Okay. Thank you so much.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Sure.

Operator

David Lewis, Morgan Stanley.

David Lewis - *Morgan Stanley - Analyst*

Good morning. Just a couple quick questions here. Mike, just on XT, I mean, a couple questions. First, the timing you are giving for mid-next year seems a little longer than maybe some more optimistic expectations, considering that it is not a novel valve. Maybe just give us a sense of -- could that estimate actually prove conservative, and what your thoughts are there? A

nd then secondarily, I would love to know kind of how you think about XT in the US, in terms of being able -- as a key growth driver next year can it really drive increased growth, or do you see XT as a valve that likely cannibalizes a lot of TA procedures? So to those two points, both the FDA process, and how you see XT playing out next year as a growth catalyst?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Well, thanks, David. I think we need to bring you with us to the next FDA meeting, so that you can explain to them that XT is not a novel valve, and that they should rapidly move to approve this. (Laughter). We try and make similar arguments, but they are pretty convinced that it is a unique and novel valve. And we are pretty pleased.

We think that profile changes change is going to be substantial. I am not sure everybody really thinks about the difference of moving from a 24 French system to a 18 French eSheath. That is a big change that customers are going to go through, and I think it is going to have a big impact on patients. In addition, I also mentioned that we have -- we will have a range of sizes that are significant, and that will make a difference as well. There is -- there are patients that are being excluded today, because we can't serve them with a 23 and 26 millimeters size.

David Lewis - *Morgan Stanley - Analyst*

Okay. And then Tom, just give me a quick follow-up on gross margins. Obviously, this year there is significant series of launches in multiple markets which are pressuring GMs. Next year you start to an anniversary some of those launches, but we kind of gear up for the US push of XT. I mean, is XT in the US going to have the same type of inventory pressure that we are seeing here in '13, or can we sort expect the broader mix of your business with the multiple countries driving [perf] valve to maybe take those GM's higher? So I am just trying to get a sense of whether the pressures we are seeing in the back half of '13, are we going to see them again in '14 because of XT, or the net benefit should be GMs heading higher? Thank you.

Tom Abate - *Edwards Lifesciences Corp - CFO*

Yes, it is difficult to predict. We need to get the actual approval dates behind us, and see how these launches are actually going to work, how aggressively we will look at inventory in both cases. But our goal is to get everything that we can outside the US to XT, including the US. So it will give us some efficiencies. Obviously S3 will be the leader, but next year it is probably mainly Europe that we are looking at.

So being able to drop SAPIEN should help. I don't know how quickly we would see that benefit. Probably a little bit of time before we get that worked through the system, because we do still have some -- we still will have some SAPIEN in some indications in the US.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. I think I will just add to Tom's answer, that although we do pick up efficiency when we leave SAPIEN and go to XT, we will be producing a more expensive SAPIEN 3 valve as we move forward so.

Tom Abate - *Edwards Lifesciences Corp - CFO*

That is true.

David Lewis - *Morgan Stanley - Analyst*

Thank you very much.

Operator

Kristen Stewart, Deutsche Bank.

Kristen Stewart - *Deutsche Bank - Analyst*

Hi, thanks for taking the question. This is a follow-up to that last one. Just in terms of the SAPIEN XT label, have you changed your view on our expectation that it will be not only approved for the inoperable patient population but also for high-risk, because I am just confused as to how you would then be able to transition everything over to SAPIEN XT without that label also specifying high risk?

Tom Abate - *Edwards Lifesciences Corp - CFO*

Yes. No, we haven't changed our view. Of course, we would love to have the label be not only inoperable but high risk. But at this point, we don't have any reason to be able to really provide any guidance on that, Kristen. If -- the trial provide -- well, you are familiar with what the trial tested.

Kristen Stewart - *Deutsche Bank - Analyst*

Right. And so, I guess if it doesn't change, then I guess we could continue to see some of this inventory pressuring gross margins, because you will have to have both product lines continue in the US, until presumably PARTNER IIa results and approval?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

I think that your broad assumption is correct. If that were to persist, then we would have to keep SAPIEN going as well as XT, as well as SAPIEN 3, that would sort of hurt our efficiencies, and we would feel that in the margin.

Kristen Stewart - *Deutsche Bank - Analyst*

Okay. And then I was wondering if you could spend expand a little bit more on just the Japanese market? I know you had mentioned that you expect the ramp to be a little bit slower. Can you maybe help us get a little bit more perspective, just on the number of centers you are looking at there, what in particular is causing this slow ramp? What centers need to be credentialed for, or anything in that regard?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Sure. So the -- we have already begun training centers. But there, in addition to what Edwards typically does, there is an additional criteria that was established by the Ministry of Health and Welfare in Japan, and medical societies for there actually to be a certification that will be done by local physicians, local societies. And that is an additional gating item, and would need to be done along the way.

So what we are concerned is, it will make the launch actually even more deliberate. So it will be -- might be a slower ramp than if we had we didn't have that requirement in there. Now having said that, we think this is going to be a very popular procedure in Japan and ultimately it is going to grow very nicely. But I think this additional requirement is going to mean that it is going to go slower. So even though we have trained some centers, for example, I doubt that we will have an additional 10 centers trained in the fourth quarter.

Kristen Stewart - *Deutsche Bank - Analyst*

Okay. And I missed in the beginning, but how many centers are in the US right now?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

265 at the end of the third-quarter.

Kristen Stewart - *Deutsche Bank - Analyst*

And do you still feel good about the targets that you had set? It seems like it is tracking a little bit lighter.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

I am sorry, Kristen, what was that?

Kristen Stewart - *Deutsche Bank - Analyst*

But do you still feel positive about the number of centers that you expect to add? That number seems to be tracking a little bit lower.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. Given where we are right now, it is probably less likely that we reach 300 by the end of the year. But we think typically the third-quarter is slow, so it is not surprising that it is a little less this quarter than we have experienced in the past. I think we need to let some others ask questions now, Kristen.

Operator

Glenn Novarro, RBC Capital Markets.

Glenn Novarro - *RBC Capital Markets - Analyst*

Thanks, good morning. Just a follow-up on Germany and a follow-up on Japan. In Germany, I believe Medtronics CoreValve was doing similar, about $15 million to $20 million per quarter. And I guess, what I am hearing you is you are saying is, in 4Q there is enough product in the channel

that you are not going to be able to really benefit, but how should we think about the benefit in 2014? Can we capture at least 50% to 75% of CoreValve? And then I have a follow-up on Japan.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. I think it is a really good question, Glenn. When we said there was minimal impact this quarter, actually our local team actually thinks there might have been slightly negative impact, as they are still working off quite a bit of this competitive inventory. But before we can make a call on how things might go in the future, I think we are going to need these decisions from the court, because the courts will tell us a couple of things.

One is, whether there is going to be a recall of the products that are still on the shelf. And two, just how rigorous this definition of compassionate is. We think it is quite rigorous. And again, we have tried to be generous with the idea that we are really going to do the very best for patients and physicians. But that is not clear. So we would expect over the next several weeks to have some decisions there that help clarify that. But it is not perfectly clear right now, Glenn.

Glenn Novarro - *RBC Capital Markets - Analyst*

And I would assume we will get the update and at the analyst day, correct?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Certainly.

Glenn Novarro - *RBC Capital Markets - Analyst*

And then just in Japan, can you remind me -- I believe in the past you have said, no stocking Japan, just consignment. Is that correct?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

That is correct. We are going to go directly to consignment model in Japan.

Glenn Novarro - *RBC Capital Markets - Analyst*

Okay. Great. Thanks for taking my questions.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Certainly.

Operator

Bob Hopkins, Bank of America Merrill Lynch.

Bob Hopkins - *BofA Merrill Lynch - Analyst*

Thanks, and good morning.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Good morning, Bob.

Bob Hopkins - *BofA Merrill Lynch - Analyst*

So just a couple quick follow-ups. First of all, on the US side, can you give us a sense as to what you expect in terms of Q4 revenue from clinical trials for US TAVI?

And then to follow-up on the question on number of centers in the US, I was wondering if you could comment on, are you still comfortable longer-term that you can have really 400 centers up and running ultimately? Or is that number now lower, because that is certainly was what some of the commentary was yesterday in a few of the sessions.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. So the -- and so the -- and I am trying to --

Tom Abate - *Edwards Lifesciences Corp - CFO*

The Q4 clinicals --

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

So the Q4 clinicals, we hesitate to make predictions about what clinical cases will be in the quarter. We think that there will continue to be some pretty good clinical volume with SAPIEN 3 beginning in the PARTNER II trial. We think that will be pretty popular, so that could drive some pretty rapid uptake. But it is difficult for us to predict exactly where that comes out.

In terms of the number of sites, yes, you are right, given that we are at 265, it does call into question on whether we would get to 400 by the end of next year. We are going to that analysis now. We will try and give maybe a sharper picture of that, when we get to the investor conference, but your observation is a good one.

Bob Hopkins - *BofA Merrill Lynch - Analyst*

So and then just as a follow-up, on the clinical trial revenue -- I know you don't want to give an exact number for Q4, but should we assume it is roughly the same as what it is right now? And then my last follow-up is simply, do you have any update for us in terms of your expectations for a decision from the European patent office on validity?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. Thanks. I admire your persistence on trying to get a clinical number out of us in the fourth quarter, but I think we are going to hesitate to offer that up. I think I have pretty much offered the best insight that I can.

In terms of the Spenser patent, we would expect the European patent office to make a decision in the first half of 2014 on the validity.

Bob Hopkins - *BofA Merrill Lynch - Analyst*

Okay. Thanks very much.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Sure.

Operator

Matt Taylor, Barclays.

Matt Taylor - *Barclays Capital - Analyst*

Can you hear me okay?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes, Matt.

Matt Taylor - *Barclays Capital - Analyst*

Great, thanks. So just wanted to ask a question about SAPIEN 3. You have got your launch expected here early next year, and you are also doing some additional clinical work in the US. So first question is, you mentioned the clinical trial drain on commercial volumes in the US. And I am curious as to how you see that evolving sequentially, meaning you have got a lot of clinical stuff going on.

But you mentioned before there is more competitive clinical trials going on at the same time. Do you think that you will actually see more clinical sales for Edwards or less because of that dynamic?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. No, I guess I would say, that we are really excited about SAPIEN 3. We think it is a terrific valve. We think clinicians are super excited about it, and the opportunity for them to implant in the US, especially in these leading centers that are in the PARTNER II trial is going to be exciting for them, and we expect them to move along at a pretty rapid pace. I don't know how fast that is going to go. Naturally, they need to go back through their IRBs, which they do for any of these changes.

I don't expect that to be onerous, but it is still a requirement. So it is tough to make the call exactly how fast that is, but we would expect it to enroll pretty fast. And that would drive the clinical sales number up.

Having said that, whether it is clinical sales or commercial sales, we are relatively indifferent. This is -- as long as we are making progress here in terms of moving the best system forward, and that the therapy is continuing to grow and be popular and help patients, we are very pleased with that.

Matt Taylor - *Barclays Capital - Analyst*

Great. And just to follow-up on the centers. There has been some speculation about the total number ultimately. Can you comment on the centers that you have trained so far, have you retained all those centers? Is your value average pretty high there, and have any centers dropped off because of one reason or another?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. I don't know any exact numbers, in terms of exactly what is going on. We don't tend to have centers that so-called drop off that I am aware of any serious numbers. I'm sure there are exceptions here and there, but for the most part I think people try and meet their minimum requirements to stay within the NCB.

Matt Taylor - *Barclays Capital - Analyst*

Great. Thanks a lot for the comments.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Sure.

Operator

Suraj Kalia, Northland Securities.

Suraj Kalia - *Northland Securities - Analyst*

Good morning, everyone.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Hi, Suraj.

Suraj Kalia - *Northland Securities - Analyst*

So Mike, if I may piggyback on the question about Germany and inventory for CoreValve, I think that is widely expected that you are going to follow the same pattern in some of the other countries, whether it is Italy, UK, so on and so forth. Can you give us some perspective of, if you all would try to preempt any of the inventory issues with CoreValve, assuming in some of the other countries you will go for litigation of the Spenser patents? And would German Court set a precedent in some of the other countries also in the interpretation?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes, I think the other countries do pay attention to what the German courts do, but I am -- I hesitate to do any projections. We just don't comment on future litigation, Saroj. And so, we really have nothing to share at this point.

Suraj Kalia - *Northland Securities - Analyst*

Fair enough. One more question, Mike. And forgive me, if this is a too forward-looking question. Obviously a lot of the centers in the US complain about profitability about TAVI. I think a lot of the centers that we talk to, have consistently started giving feedback that the peri operative and immediate post-op outcomes have improved substantially, but it is the cost of effectiveness which is killing them. Do you think given all the competitive clinical trials coming on board, do you -- what does your internal analysis suggests on the price elasticity of demand on the commercial side for your products? Do you think it is a viable strategy at this time, in terms of causing a step change in the demand curve?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. Just broadly, we think although everybody is not there at this point, we think more than half the centers are profitable just on a per procedure basis today, and that that is improving. And we have seen that results in the early data that we have had a chance to look back, the MedPar data, and we are feeling that in our own experiences.

In terms of our pricing and the role in that, we think our pricing is fair, and we think it does a good job of reflecting the value of the procedures. Even if you go back to the PARTNER trial and cohort B, and remember that cost effectiveness versus other cardiovascular procedures, it was pretty comparable. And when you consider that it is a young procedure, and that there is a large opportunity for improvement, we think we are pretty well-positioned for that to continue to get better over time, especially as we are able to bring better systems that are going to be easier for patients and their physicians.

Suraj Kalia - *Northland Securities - Analyst*

Thank you for taking my questions.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Sure.

Operator

Rick Wise, Stifel.

Rick Wise - *Stifel Nicolaus & Company - Analyst*

Thanks for taking the question. Mike, two things. First briefly, I hate to ask or even think about Mike's departure -- or Tom's departure, but any update on timing of the CFO search?

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Yes. The CFO search has gone really well, Rick. We are going to be sorry to say goodbye to Tom as well. He has been a fantastic partner. He has continued to be highly engaged, and so we are expect a very smooth transition. I think that we will have something to announce certainly before year-end, hopefully even sooner than that. So just stay tuned, but that is all going well.

Rick Wise - *Stifel Nicolaus & Company - Analyst*

Good. CENTERA, a couple questions to finish for me, you said you are starting a second trial. Maybe a couple things around CENTERA, Mike, and you could just take it at whatever order you want. What does this all imply for a new trial, a second trial imply for EU approval? Do you think you

can still come to market in 2014? You talked about a new delivery system. I think you said -- it went by sort of quickly. And any larger reflections as the repositionable era grows closer? Thanks.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Sure, Rick. So, yes, we are really excited about the CENTERA valve. We think it has the potential to be by far the best-in-class self-expanding system. We decided to make a pretty significant change to the delivery system. And so, we are going to start the trial with the new delivery system here in the next several months, and that will pick up the clinical cases. We don't have any timing to project. Maybe we will have some things that we can talk about at the investor conference. But we are pleased with the direction that this is going in, and we are really looking forward to starting this next series of patients.

Rick Wise - *Stifel Nicolaus & Company - Analyst*

Thank you.

Mike Mussallem - *Edwards Lifesciences Corp - Chairman and CEO*

Sure. Okay. Well, thanks for your continued interest in Edwards. Tom and David and I will welcome any additional questions by telephone. And with that, back to you, David.

David Erickson - *Edwards Lifesciences Corp - VP, IR*

Thank you for joining us on today's call. Reconciliations between GAAP and non-GAAP numbers mentioned during this call which include underlying growth rates, sales results excluding currency impacts, and amounts adjusted for special items are included in today's press release, and can also be found in the Investor Relations Section of our website at edwards.com.

If you missed any portion of today's call, a telephonic replay will be available for 72 hours. To access this, please dial 877-660-6853 or 201-612-7415 and use passcode 421584. I will repeat those numbers for you, area code 877-660-6853 or 201-612-7415 and the passcode is 421584. Additionally, an audio replay will be archived on the Investor Relations Section of our website. Thank you very much.

Operator

Ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. Thank you for your participation, and have a wonderful day.

EXHIBIT E

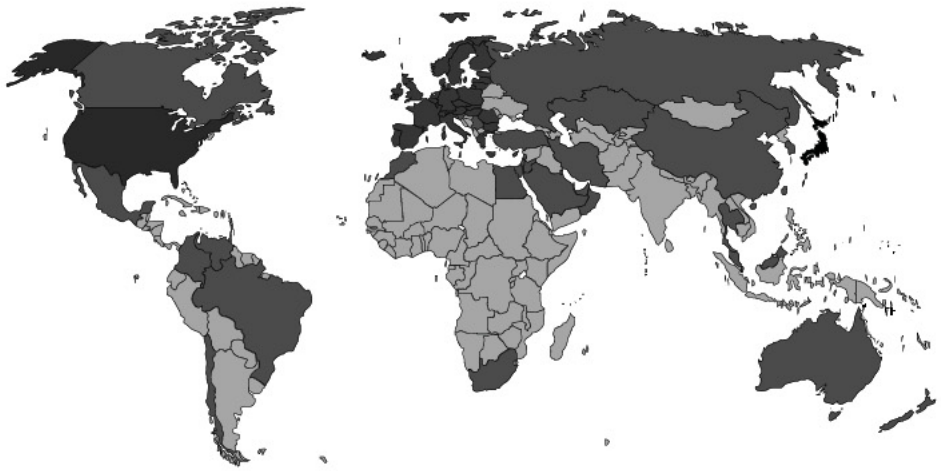
Edwards Lifesciences

Transcatheter Heart Valves

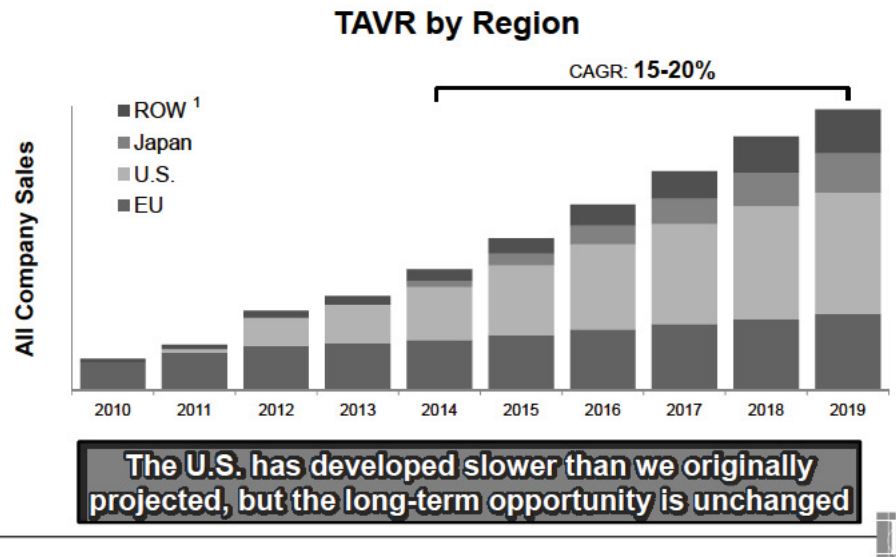
Larry L. Wood

Corporate Vice President,
Transcatheter Heart Valves

Edwards TAVR is Currently Serving Patients in Over 60 Countries



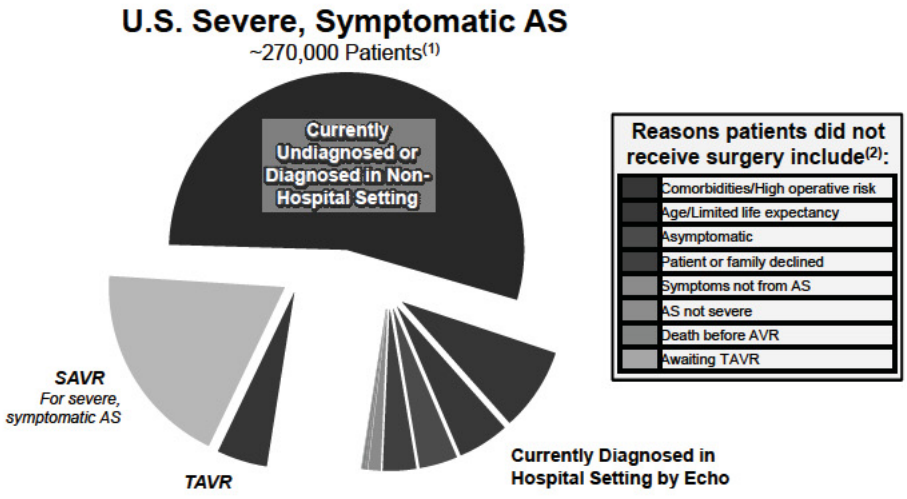
Global TAVR Expected to Reach Approximately $2.5 - $3.0B by 2019



The U.S. has developed slower than we originally projected, but the long-term opportunity is unchanged

 (1) ROW: Rest of World (EEMEA, Canada, Asia Pacific, Latin America)

While Under-Treatment is High, Will a Far Less Invasive Therapy Drive Patients to be Treated?



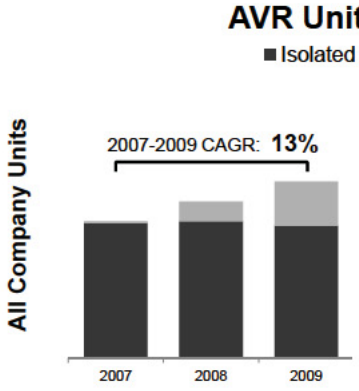
12/9/13

(1) Nkomo 2006, Iivanainen 1996, Aronow 1991, Bach 2007, Freed 2010, Iung 2007, Pellikka 2005, Internal estimates
(2) Bach, D. Prevalence and Characteristics of Unoperated Patients with Severe Aortic Stenosis. J Heart Valve Dis. May 2011. *(n=406)*

5

Edwards

In the First Three Years of TAVR in Germany, Isolated AVRs Grew About 13%



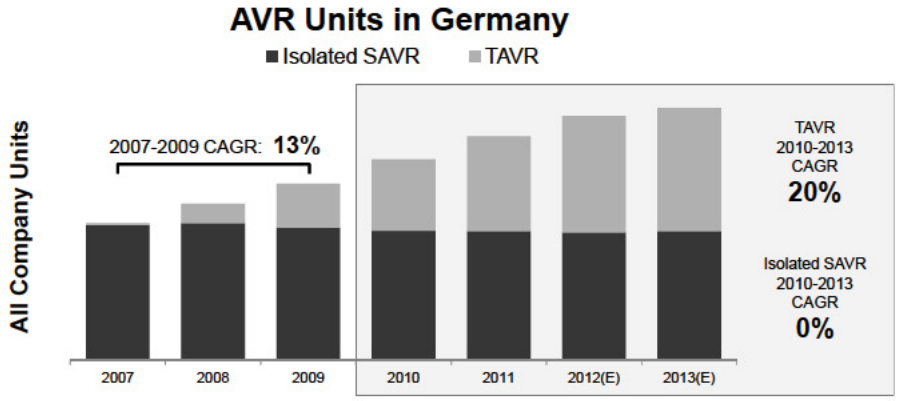
12/9/13

Includes Edwards and competition. SOURCE: Funkat et al. "Cardiac Surgery in Germany during 2011." *Thorac Cardiovasc Surg.* 2012

6

Edwards

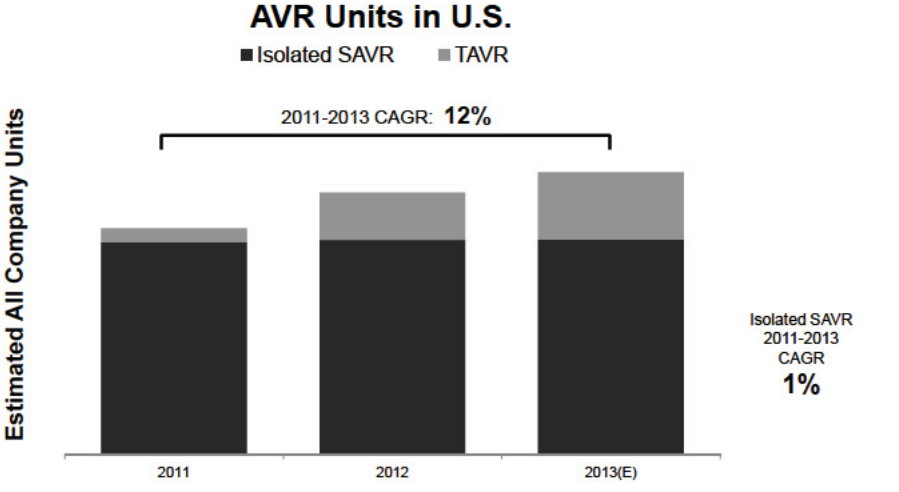
Isolated AVRs Doubled in 7 Years in Germany



TAVR growth in Germany did not come primarily from existing surgical patients

12/9/13 Includes Edwards and competition. SOURCE: Funkat et al. "Cardiac Surgery in Germany during 2011." *Thorac Cardiovasc Surg.* 2012. Data for 2012 and 2013 are based on estimates. 7 Edwards

Since Introduction of TAVR in U.S., Isolated AVRs Have Grown Significantly

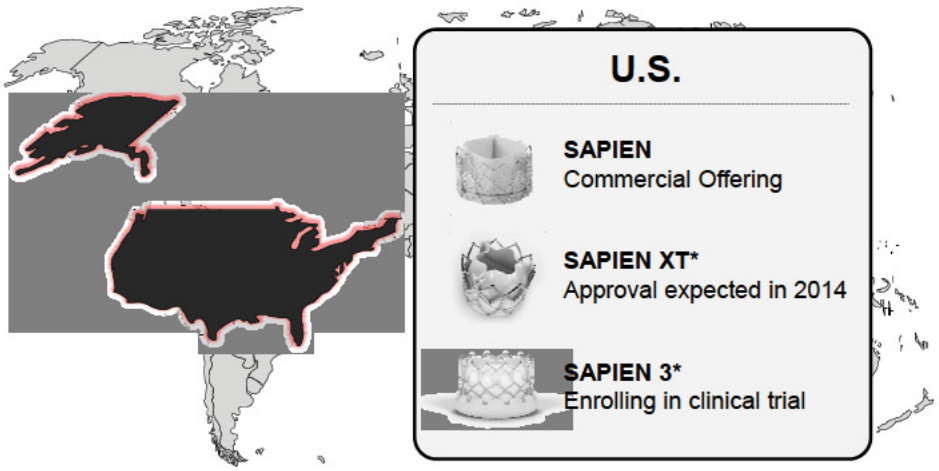


12/9/13 SOURCE: Internal Estimates of Edwards and competition 8 Edwards

Longer-Term, TAVR Could Expand Dramatically

- **Only the sickest patients qualify today**
  - A successful PARTNER II trial and continued durability of clinical results would expand this treatment
- **Longer-term, moderate and low-risk patients may seek their treatment**
  - Younger patients are often undiagnosed or postpone treatment
  - Skills, techniques, and devices are improving rapidly
  - TAVR outcomes, attractive cost profile, rapid recovery, and QoL benefits would encourage earlier treatment

In the U.S., Approval of SAPIEN XT is Expected Next Year



* The Edwards SAPIEN XT and SAPIEN 3 systems are investigational devices and are not available for commercial sale in the U.S.